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Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 101 and 120

Preliminary Regulatory Impact Analysis and Initial Regulatory Flexibility Analysis of the Proposed Rules to Ensure the Safety of Juice and Juice Products; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 101 and 120

[Docket Nos. 93N–0325 and 97N–0296]

RIN 0910–AA43

Preliminary Regulatory Impact Analysis and Initial Regulatory Flexibility Analysis of the Proposed Rules to Ensure the Safety of Juice and Juice Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Preliminary regulatory impact analysis.

SUMMARY: The Food and Drug Administration (FDA) is publishing the preliminary regulatory impact analysis (PRIA) that it has prepared under Executive Order 12866 and initial regulatory flexibility analysis (IRFA) that it has prepared under the Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement and Fairness Act (SBREFA), on the costs and benefits of FDA's proposed regulations regarding the Hazard Analysis Critical Control Points (HACCP) and labeling for juice and juice products. FDA is issuing those proposals because of recent outbreaks of foodborne illness and deaths caused by consumption of juice products that were not pasteurized or otherwise processed to control pathogenic microorganisms. Those proposals are intended to ensure that juice and juice products are safe.

DATES: Submit written comments by May 26, 1998 on aspects of this analysis related to labeling for juice and juice products and by July 8, 1998 on aspects of this analysis related to HACCP for juice and juice products.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Comments should be identified with the docket numbers found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: David J. Zorn, Center for Food Safety and Applied Nutrition (HFS–726), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4729.

SUPPLEMENTARY INFORMATION:

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I. Background

This document constitutes FDA's PRIA and IRFA of the proposed rules to amend the food labeling regulations and to require HACCP for juice and juice products. Because the industries affected by both proposed rules substantially overlap and because both proposals address the same public health problem, the safety of juice and products containing juice, the agency has chosen to analyze the economic impact of both proposed rules in a single PRIA and IRFA. These documents analyze both the costs and benefits of the proposed rules as well as the expected impacts on the affected small entities. FDA has found that these rules may constitute significant rules under Executive Order 12866 because they could have a significant impact on one sector of the economy (producers of minimally processed juice). In addition, FDA has determined under the RFA that each proposal would present a significant impact on a substantial number of small entities.

II. Introduction

FDA has examined the impacts of these proposed rules under Executive Order 12866. Executive Order 12866 directs Federal agencies to assess the benefits and costs of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Under the Executive Order, a regulatory action is ''significant'' if it meets any one of a number of specified conditions, including having an annual effect on the economy, competition, or jobs, or if it raises novel legal or policy issues. FDA finds that each of these proposed rules may constitute a significant regulatory action as defined by Executive Order 12866, as discussed as follows.

In addition, FDA has determined that these rules are not significant rules under the Unfunded Mandates Reform Act of 1995 (UMRA) requiring benefit-cost and other analyses. Under UMRA significant rule is defined as ''a Federal mandate that may result in the expenditure by State, local and tribal governments in the aggregate, or by the private sector, of $100,000,000 (adjusted annually for inflation) in any 1 year''.

Finally, in accordance with the SBREFA, the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget (the Administrator) has determined that these proposed rules are major rules for the purpose of congressional review. A major rule for this purpose is defined as one that the Administrator has determined has resulted or is likely to result in an annual effect on the economy of $100 million or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets.

III. Factors Considered in Developing This Analysis

This analysis estimates costs and benefits for two proposed regulations, published in the **Federal Register** of April 24, 1998 (63 FR 20450 and 20486), that would affect the safety of juice products. The first rule requires warning statements on minimally processed packaged juice. That is, juice that has not been processed in a manner that will produce, at a minimum, a 5-log reduction, for a period at least as long as the shelf life of the product when stored under normal and moderate abuse conditions, in the pertinent microorganism. The ''pertinent microorganism'' is the most resistant microorganism of public health significance that is likely to occur in the juice. In the remainder of this analysis, this will be referred to as the ''5-log reduction.''[1] The second rule requires manufacturers of most juice to implement a HACCP program with the same 5-log reduction performance criteria. However, FDA is proposing to exempt retailers who, for the purposes of this rule, the agency has tentatively decided will include very small businesses that make juice on their premises and whose total sales of juice and juice products do not exceed 40,000 gallons per year and who sell directly to consumers or directly to consumers and other retailers.

The effective date for the labeling rule is proposed to be 60 days following publication of the final rule with

[1] That is, the total combined effect of all controls have the effect of reducing the number of colony forming units (cfu's) by a factor of 100,000. This implies that even if the product should contain 1,000 cfu's per gallon (gal.) prior to processing, the final product after processing would contain only .01 cfu's per gal.

warning statements required either on the labels or, in the case of products which do not bear the warning statement on the label, on labeling (e.g., on signs or placards at the point of sale) on juices that have not been processed in a manner that will produce, at a minimum, a 5-log reduction. Packaged juices produced by large firms are required to bear warning labels beginning on January 1, 2000, and packaged juices produced by small and very small firms[2] are required to bear warning labels beginning on January 1, 2001. The agency expects that the HACCP rule, because of its complexity, will not be finalized for at least 1 year following finalization of the juice labeling rule. The HACCP rule is proposed to be effective for large firms, 12 months following publication of the final HACCP rule; for small firms, 24 months following publication of the final HACCP rule; and for very small firms, 36 months following publication of the final HACCP rule. For purposes of this rule, the agency is proposing to define large processors as those who have more than 500 employees, small processors as those who have less than 500 employees and very small processors as those who have either: (1) Total annual sales of less than $500,000, or (2) that have total annual sales of greater than $500,000 but total annual food sales of less than $50,000, or (3) that employ fewer than 100 full-time equivalent employees and annually sell less than 100,000 units of the juice in the United States.

To a large extent, benefits and costs will depend on how processors of juice who do not currently implement controls sufficient to achieve a 5-log reduction respond to the warning label regulation. That is, firms will choose whether to display the warning statement or to comply early with the 5-log reduction. The agency has no information to indicate the choices that specific processors will make.

The actual choice that each processor will make depends on several factors: (1) The revenue that processors expect to lose because of consumers' responses to the Government's announcement of the rules and the warning label, (2) the costs of and length of time allowed to make label changes, (3) the costs of achieving a 5-log reduction in pathogens, and (4) the revenue that processors expect to lose if consumers respond negatively to the changes in product characteristics caused by processing the juice.

Processors will choose to discontinue juice production if they perceive that either labeling or a change in processing practices will lower profits below a ''normal'' return.[3] In other words, processors will go out of the juice business rather than comply with these regulations only if one of the two following conditions is satisfied: (1) The combination of the cost of displaying the warning labeling and the reduction in revenue caused by the negative response of consumers to the warning results in below normal profits; or (2) a combination of increased costs from processing and a reduction in revenue caused by the negative response of consumers to the changes in product quality results in below normal profits.

For the purposes of this analysis, the agency has assumed that, in order to avoid having their products associated with the warning to consumers, all establishments that will eventually be covered by the HACCP rule will implement controls sufficient to achieve a 5-log reduction when the labeling rule takes effect. The agency has also assumed for the purposes of this analysis that those establishments not covered by the HACCP rule will display the warning statement for packaged juice products. However, in order to avoid displaying the warning statement, these establishments may choose to process their juice in a manner sufficient to achieve a 5-log reduction in pathogens or under an adequate voluntary HACCP plan.

IV. Regulatory Options

The preambles in the accompanying proposed regulations describe the compelling public need for these regulations. For example, in recent years, pathogens have been discovered in fresh juices after having caused severe illness in humans. These products were previously not known to be vehicles for such hazards, given their low pH. Because these events have occurred, the agency tentatively finds that it is prudent to require the adoption of preventative controls for hazards now associated with juice where controls may not have been previously thought to be necessary.

There are a number of regulatory options that FDA has preliminarily considered to reduce the risks associated with consuming juice products. FDA requests comments on benefits, costs, and any other aspect of these options.

A. Take No New Regulatory Action

Choosing this option would imply either reliance on: (1) Existing Federal regulation, (2) State and local regulatory activity, (3) business interests, (4) consumer demands, and (5) product liability pressures to reduce risks incurred by consumers of juice products or acceptance that the risks that juice currently presents are risks that consumers are unwilling to pay to reduce. In the first case, it is unlikely that the market will adjust to eliminate the risks present in juice because of the difficulty of establishing the link between the various kinds of illnesses, whether acute or chronic, to consumption of juice. Generally, this link may only be established when there are large, geographically focused outbreaks of acute illness. However, research indicates that most cases of foodborne illness are sporadic and geographically dispersed and not associated with any identifiable and focused outbreaks (Ref. 1). In the second case, it is presumed that consumers are willing to pay to reduce these risks given the sizeable estimated benefits of the proposed rules. Finally, while industry and State governments have undertaken steps in many areas to reduce risks associated with juice, FDA believes that the changes have been made with the expectations of Federal regulation. It is unlikely that the market would fully adjust to reduce the risk without additional Federal action.

B. Regulate Only High-Risk Juice Products or High-Risk Hazards

FDA could choose to make these rules applicable only to juice products that have been associated by epidemiology or by inspection history with health hazards. This option is discussed in the appendix supporting this analysis (Ref. 9). In the appendix, the agency concluded that unpasteurized or otherwise nonheat treated juices present the largest risk to consumers because pathogens pose the highest risk of the several categories of hazards. FDA is proposing that all chemical, physical, and biological hazards be included under HACCP, despite the differences in relative risk posed by different types of hazards. It is important to note that processors may, under the umbrella of

[2] The labeling rule does not define ''very small firms'' but the HACCP rule does give a separate definition of ''very small firms'' as a subset of ''small firms'' as defined in the labeling and HACCP rules. Therefore, the term ''very small firms'' has been used here in relationship to the labeling rule to make clear where this subset fits in the context of both of these rules. The HACCP rule defines small businesses as those with fewer than 500 employees. It defines very small businesses as those with total annual sales of less than $500,000 or those with total annual food sales of less than $50,000 or those with fewer than 100 employees and less than 100,000 units of juice sold annually.

[3] A normal return on profits is the average market return on capital that a processor could receive, for example, by investing in the stock market.

HACCP, adjust for the probability and severity of hazards by adjusting critical limits, the frequency of monitoring, intensity of corrective action, or any number of other margins. FDA has not evaluated the benefits and costs of structuring HACCP based on this option, and seeks comments on it, especially on the option of covering only some types of juice.

C. Do Either One of the Proposed Rules but Not Both

One option would be to eliminate the HACCP requirement for juices, one of the two proposed actions, and only require that juices that are not processed to achieve a 5-log reduction be labeled with a warning to consumers. The purpose of this labeling is to alert consumers who are at increased risk to avoid these products and to inform all consumers of the risk of these products relative to other juices. However, it is difficult to predict what products consumers would switch to once they encounter the warnings. It is possible that some consumers may reduce their health status by choosing less nutritious substitutes in order to avoid the products with the warning labels. Although labeling may be effective for changing both producer behavior (particularly to avoid displaying the warning) and consumer behavior, the agency believes that labeling alone is unlikely to be sufficient to address all health hazards associated with consumption of juice products.

Another option would be to eliminate the labeling rule and only require that juice processors implement HACCP. This option would reduce the possibility that some consumers might overreact and avoid all juice. This option would also allow fresh juice to be marketed without warnings and would result in some cost savings for products that will not need to pay for labeling costs. However, it would also result in some reduction in benefits because the HACCP rule will take longer to implement than the labeling rule and because the proposed labeling rule covers juice made at the point of sale and the proposed HACCP rule does not cover retailers.

D. Require New Current Good Manufacturing Practices

FDA could develop and require current good manufacturing practices (CGMP's) or sanitation standards specific to juice products to improve the safety of juices. The use of CGMP's would assist processors in ensuring the safety of their juices by providing guidance on how to reduce insanitary manufacturing practices and on how to protect against food becoming contaminated. While FDA currently has general CGMP's that provide guidance to all food processing industries, it does not have specific CGMP's for the juice industry.

There are three reasons that this alternative alone may be undesirable. First, CGMP's by themselves are unlikely to have a sufficient impact on the safety of juice, particularly relative to HACCP. That is, CGMP's do not provide: (1) A structure for each processor to align specific hazards unique to the processor's operations with specific control measures; (2) assurance that the processor will establish specific performance standards appropriate to the processor's unique operation; (3) records that document that the performance standards are met; and (4) records of frequent audits to verify that controls are being applied, all of which are associated with HACCP. Identifying specific hazards, designing controls that are specific and unique to each operation, and verifying that these controls are being applied as specified are essential elements of a control program that will provide an improved level of food safety.

Secondly, under the HACCP approach being proposed, the industry is required to use FDA's general CGMP's in part 110 (21 CFR part 110) and to develop and adopt sanitation standard operating procedures (SOP's) as part of their prerequisite programs for their HACCP plan. Therefore, the HACCP approach builds on the foundation of CGMP's at the same time it avoids the limitations of this alternative.

HACCP is designed for use in all segments of the food industry from growing, harvesting, processing, manufacturing, distributing, and merchandising to preparing food for consumption. Prerequisite programs such as current good manufacturing practices (CGMP's) are an essential foundation for the development and implementation of successful HACCP plans.

The production of safe food products requires that the HACCP system be built upon a solid foundation of prerequisite programs. Each segment of the food industry must provide the conditions necessary to protect food while it is under their control. This has traditionally been accomplished through the application of CGMP's. These conditions and practices are now considered to be prerequisite to the development and implementation of effective HACCP plans. Prerequisite programs provide the basic environmental and operating conditions that are necessary for the production of safe, wholesome food.

E. Require Pasteurization

FDA could require that all juice be pasteurized rather than requiring HACCP with a specified 5-log reduction. Although FDA is not currently aware of other practical methods to achieve this level of control, solely requiring pasteurization would inhibit new technological innovation and it would only address one type of hazard (pathogens that are not heat resistant). In this analysis, the agency has, in fact, evaluated the costs of pasteurization for those juices not now pasteurized. It should be pointed out that, by volume, the vast majority of juices are now pasteurized or otherwise equivalently treated. Thus, the marginal costs and benefits of requiring pasteurization only apply to the small fraction of juice that is not heat treated.

The agency requests comment on the appropriateness of the 5-log reduction performance standard and if other approaches, such as establishing a minimal acceptable risk standard for juices, could be used that would ensure the safety of the juice. The agency requests comments on what such a minimal acceptable risk standard should be and how it would be implemented. The agency also invites interested persons to submit scientific data concerning the acceptability of a 5-log reduction requirement or whether a more or less stringent performance standard (e.g., 3- or 7-log reduction) for specific juices would be more appropriate or whether different approaches consistent with a minimal acceptable risk standard for juices might be appropriate for specific juices based on their unique characteristics.

F. Set Different Performance Standards for Processing of Different Products

One regulatory option would be to establish different performance standards for processing different types of juice products to decrease the number of pathogens. In the proposal, the agency has tentatively proposed that any combination of processing steps which cumulatively result in a 5-log (a 100,000-fold) reduction in pathogens should be applied to the production of all types of juice. However, different products may warrant different processing stringencies because of a number of factors, including: (1) The initial microbial counts on raw produce are likely to vary, (2) different types of produce are likely to harbor different kinds of pathogens, and (3) different products provide different environments for microbial growth. This

option could either be exercised as part of the final rule in response to comments or the proposed standards could remain with the option to further petition the agency for a different standard. The benefits and costs of the standard will vary directly with the stringency of different performance standards. However, FDA does not have data to estimate preliminarily the costs and benefits of this option.

G. Expand HACCP Rule Coverage

FDA has tentatively concluded that the retail sector should not be included in the HACCP rule and has asked for comments on the appropriateness of this conclusion. The expansion of coverage of the HACCP rule to include retailers that process juice at the point of sale would add an estimated additional 14,300 restaurants and 1,300 grocery stores and supermarkets for a total of approximately 16,000 establishments. If the cost for these establishments to implement HACCP was equivalent to that of very small processors who would be required to initiate pasteurization ($26,000 in the first year and $11,900 in subsequent years), then the total additional cost of this option would be approximately $416 million in the first year and approximately $190 million in subsequent years. However, the agency does not have direct information about the cost of implementing HACCP in a retail setting for juice and the actual costs may vary significantly from these estimates.

H. Use of One of Various Alternatives

An alternative approach to mandating HACCP would be to provide a more flexible array of options tailored to the microbial risk present in the particular juice. Manufacturers of apple cider would be provided a permanent option choosing between labeling or implementing a HACCP program with a 5-log pathogen reduction. All juices other than untreated apple cider would be provided a permanent option of choosing between labeling, implementing a HACCP system, or achieving a 5-log pathogen reduction. However, FDA believes that this option provides only weak incentives for processors to implement a HACCP system. Processors could label hazardous products without taking steps to improve the safety of juice or choose to achieve a 5-log reduction for microbial pathogens without addressing other hazards. The agency believes that labeling would not achieve the same level of product safety. Additionally, there would be less incentive for processors to implement a HACCP system, which includes, among other things, developing and implementing sanitation SOP's and recordkeeping at critical control points in addition to achieving a 5-log reduction. Other hazards that would not be addressed include chemical contaminants, hazardous metals, including lead and tin, mycotoxins, pesticides, and physical hazards, such as glass.

Another regulatory option would be to include labeling for unpackaged juice products for all retail outlets, such as restaurants. This option would also require any very small retailer (as defined for the purposes of this rulemaking) who is manufacturing less than 40,000 gallons of juice per year and selling it directly to consumers and other retailers to either label or achieve a 5-log kill until a requirement for HACCP would become effective 36 months from the date of publication of the final rule.

If this option is combined with both proposed rules, FDA has estimated the benefits to be $383 to $478 million annually and estimated the costs in the first year to be $54 million and the costs in subsequent years to be $28 million.

V. Benefits

This analysis provides estimates of three additive, independent benefits of these two proposed rules: (1) Reduced expenditures related to regulatory enforcement, (2) reduced adverse health effects, and (3) other benefits. To some extent, the benefits of the two rules are intertwined. Because of the earlier compliance dates, the impact of the labeling rule will be to achieve some of the benefits faster. That is, if firms choose to achieve a 5-log reduction through their processing practices to avoid labeling, then some of the future benefits that would be otherwise achieved under HACCP will be achieved sooner because of the incentive provided by the labeling rule. Also, if at-risk consumers avoid unpasteurized juices as a result of the labeling, there will be reduced adverse-health effects prior to the introduction of HACCP. On average, the labeling rule will achieve some of the benefits 2 years faster than the HACCP rule.

A. Enforcement Benefits

To the extent that these proposed rules are effective at reducing contaminated juice, they should reduce the number of safety-related enforcement actions (for both domestic and imported products) taken by the agency for juice products. The enforcement activities chosen as a baseline for juice products fall between the period 1992 and 1996 (inclusive) and involve import detentions and domestic recalls.

In the final regulatory impact analysis for FDA's seafood HACCP rule, FDA used an assumption that the rule would prevent 50 percent of the current number of annual enforcement actions. The agency did not receive comments on this assumption in that rule and does not yet have data from implementation of the rule to validate it. However, this may be a conservative assumption. If HACCP plans are properly conceived, implemented and validated, it is likely that the vast majority of problems will be caught and corrected in the plant, rather than result in foodborne disease outbreaks or be caught through Federal sampling of the final product. Thus, the agency will continue to make this assumption but requests comment on it.

1. Import Enforcement

Over the period 1992 through 1996, there were a number of imported juice products detained for various violations of the Federal Food, Drug, and Cosmetic Act (the act). A detention is a procedure for preventing violative products from entering the United States. Following a determination that a sample of a product is violative, three steps occur: (1) FDA sends a detention notice to the importer providing an opportunity to introduce testimony as to the condition of the product; (2) the importer may contact an attorney, submits a response application, and introduces evidence regarding the product; and (3) FDA makes a determination about what should be done with the shipment. There are three actions that FDA can specify for a detained shipment: (1) The product is allowed to be ''reshipped'' out of the country, (2) the product is reconditioned so as to bring it into compliance with U.S. law, or (3) the product is destroyed under Federal supervision. Assume that the cost per shipment of the three steps to all parties involved is $5,000. Then the remaining cost of detention is the cost per shipment of the three actions which is related to the value of the shipment.

Table 1 gives the number of shipments detained and the total dollar value of juice products detained for violations of the act for the entire period 1992 through 1996.

The average value per shipment of imported juice products refused entry is approximately $10,000. The average number of imported juice product shipments detained annually is 23.

TABLE 1.—TOTALS OF JUICE IMPORT DETENTIONS FOR 1992 THROUGH 1996 BY REASON FOR DETENTION

Reason for Detention	Food Additive Issues	Poisonous or Deleterious Substances	Violative Pesticide Residues	Chemical Contamination	New Drug Residues	Microbial Hazards	Total
Number of Shipments	44	17	53	1	1	1	117
Value of Shipments	$122,000	$112,000	$802,000	$79,000	$20,000	$2,000	$1,137,000

If, on an annual basis, 23 imported juice product shipments are detained at an average Federal enforcement and industry negotiation cost of $5,000 per shipment (60 FR 65189), and if all 23 shipments (with an average value of $10,000 per shipment) are destroyed so that the entire $10,000 value of the shipment is lost, then the total annual cost of all juice detentions is approximately $345,000 (23 shipments x ($10,000 value of shipment + $5,000 enforcement and negotiation cost)). If 50 percent of these enforcement costs are prevented, then the benefits related to import enforcement are approximately $175,000.

2. Recalls

Recalls tracked by FDA for pathogens or pesticides in juice products are infrequent. For the period 1992 through 1996 there was one class 1 recall and there were seven class 2 recalls[4] for such hazards, or about two recalls per year. A class 1 recall may cost as much as $3 to $5 million between expenditures by the manufacturer, retailers and State, local, and Federal authorities. However, the typical juice recall is smaller and less costly than this. If the combination of industry and government costs per recall on average is $1 million, then the total annual cost of juice recalls is approximately $2 million (2 recalls per year at $1 million each). This assumption is based on FDA conversations with industry for both large and small recalls. FDA acknowledges that this may not be the true average cost of a recall and requests comment on this assumption. If 50 percent of these enforcement costs are prevented, then the benefits related to recalls tracked by FDA are $1 million. However, FDA may not be aware of all recalls that take place, particularly for less hazardous reasons. Assuming that the recalls that FDA is not aware of are considerably smaller, perhaps costing $100,000, and that FDA may only hear about 10 percent of such recalls, then the total annual cost of such recalls could be $1 million. If 50 percent of these enforcement costs are prevented, then the benefits related to recalls not tracked by FDA would be $500,000. Thus, the total annual benefits of the HACCP rule related to recalls is estimated to be $1.5 million.

In addition to those benefits, when firms have recalls that are made public they will generally suffer a loss of sales, at least temporarily, from lost ''goodwill.'' This alone does not result in a social cost but rather a social transfer as other firms will step forward to capture sales lost from the recalling firm. However, in addition to the resources invested in recalling the product, the recalling firm may invest real resources in advertising to recapture lost goodwill, a social cost. FDA cannot quantify this cost.

B. Health Benefits

This section presents quantitative estimates of health benefits from this rule. This is accomplished by the following steps:

1. The most significant hazards in juice are described in terms of severity and duration;
2. The hazards are described in terms of resulting health effects and symptoms when they cause illness;
3. The health effects and symptoms are translated into consumer utility losses;
4. The utility losses are translated into values in terms of lost dollars (this gives the cost per case for every combination of level of severity and for the specified duration for each hazard);
5. The average annual number of reported cases associated with juice are distributed according to the percentages associated with each level of severity;
6. The factors used to account for under reporting of foodborne illness are estimated;
7. The reported cases are multiplied by the under reporting factors to get the estimated average annual number of cases;
8. The percentages of each type of hazard expected to be prevented by the proposal are listed; and
9. The total health benefits of the proposal are derived by multiplying numbers 4, 7, and 8.

That is, TB = RC x CF x CR x V, where
TB = total health benefits in dollars,
RC = number of reported cases,
CF = under reporting correction factor,
CR = percent of cases reduced,
V = dollar value per case averted (medical costs + value of pain and lost function).

1. Description of Microbial Hazards in Juice

Most of the significant health risks associated with juice products are microbial. In the last 5 years the hazards associated with commercially processed, packaged juice produced by nonretail establishments include *Bacillus cereus*, *Escherichia coli* O157:H7, and *Salmonella* non *typhi*.[5] Table 2 lists these hazards with associated severities and duration of severities. These hazards have been directly linked to orange and apple juice products. However, all juices take farm produce as an input; all use similar types of processing steps; and all are distributed in similar ways. Therefore, although other types of juices are less likely to be associated with foodborne disease outbreaks primarily because consumption of orange and apple juice greatly exceeds consumption of all other types of juice combined, all juices are similarly vulnerable to microbial contamination. All juices are sensitive to potential contamination by pathogenic microorganisms due to the way fruits and vegetables are grown and harvested.

Based on current scientific understanding, potential vehicles or mechanisms for pathogenic cross contamination common to most fruit and vegetable harvesting and juicing operations include water; manure fertilizer; worker, field, and facility sanitation and transportation, handling and processing. While most of the potential for contamination would appear on the surface of the fruit or vegetable, the process of juicing this

[4] Class 1 recalls are for dangerous or defective products that predictably could cause serious health problems or death. Class 2 recalls are for products that might cause a temporary health problem, or pose only a slight threat of a serious nature.

[5] Most of the information in section V of this document (Benefits) is taken from Ref. 9. It includes hazards other than those for which benefits have been estimated in this analysis. The hazards considered in section V of this document are those for which the risk is highest. That is to say they are the most significant in terms of probability of occurrence and severity.

fruit or vegetable would potentially incorporate the pathogenic microorganisms into the final juice product. Ref. 10, page 31, lists the pH of some fruit and vegetable juices.

TABLE 2.—DESCRIPTION OF MICROBIAL HAZARDS IN JUICE

Hazard	Severity	Percent[3]	Duration of Illness (days)
E. coli O157:H7			
	Mild	50	5
	Moderate	32	9
	Severe-acute	18	32
	Severe-chronic	2	26,645[1]
	Death	1	
Salmonella (non *typhi*)			
	Mild	65	2
	Moderate	30	5
	Severe	5	17
	Reactive arthritis-short term	2	25
	Reactive arthritis-long term	5	18,250[2]
	Death	.1	
B. cereus			
	Mild	99	.75
	Moderate	1	1
	Severe	0	NA
	Death	0	NA

[1] Symptoms lasting 26,645 days, or 73 years, implies that it is generally very young children who experience these severe chronic effects (Ref. 2–3).
[2] Symptoms lasting 18,250 days, or 50 years. This estimate and other information in section V of this document (Benefits) relating to reactive arthritis are taken from Ref. 10.
[3] Percentages are taken from Ref. 10.

Symptoms of illness that results from exposure to each hazard may be classified as mild, moderate, or severe. In general, mild cases are not brought to the attention of a medical professional. Moderate cases receive medical attention but do not require hospitalization. Severe cases involve hospitalization and some of these result in death. The ''Percent'' column in Table 2 gives an estimate of the percentage of the total number of cases that are classified in these four categories of severity for each hazard. Note that the categories are not necessarily mutually exclusive, for example, severe-chronic cases of *E. coli* O157:H7 follow only after severe-acute cases of *E. coli* O157:H7, and deaths follow only after severe cases. However, the ''Percent'' column reports each category of severity as a percentage of total cases so that there is no double counting. Another factor that tends to distinguish the categories of severity is the duration of time that symptoms are experienced. The ''Duration'' column gives the general duration of symptoms (in days) that are associated with the categories of severity for each hazard.

2. Description of Health Effects and Symptoms of Microbial Hazards in Juice

In order to quantify the loss (disutility) that individuals experience from becoming ill, the pain, suffering, and mobility loss must be scaled. Tables 3, 4, and 5 represent the outcome of one type of scaling of these effects. Individuals who become ill experience different levels of functional status in terms of mobility, ability to do other physical activity, and ability to engage in social activities. The ''Functional Status Code'' column in Table 3 represents the status code which correlates with the categories of severity for each hazard. Individuals who become ill also experience additional disutility due to the symptoms of the illness. The ''Symptom/Problem Complex Code'' column represents the symptom/problem complex codes which correlate with the categories of severity for each hazard. Descriptions of the functional status and symptom/problem complex codes are given in Tables 4 and 5. FDA requests comment on this scaling model.

TABLE 3.—DESCRIPTION OF HEALTH EFFECTS AND SYMPTOMS OF MICROBIALLY RELATED ILLNESSES IN JUICE

Hazard	Severity	Functional Status Code[1]	Symptom/Problem Complex Code[2]
E. coli O157:H7			
	Mild	L20	8, 12, 13, 29
	Moderate	L19	8, 12, 13, 16, 19, 29, 32
	Severe-acute	(L1 x .2) + (L6 x .8)[3]	8, 12, 13, 16, 19, 29, 32
	Severe-chronic	L31	9
Salmonella (non *typhi*)			
	Mild	L20	12, 13, 29
	Moderate	L20	12, 13, 29
	Severe	L6	12, 13, 16, 29
	Reactive arthritis	L35, L41, L42, L43[4]	19
B. cereus			
	Mild	L19	12, 13, 29
	Moderate	L19	12, 13, 29

TABLE 3.—DESCRIPTION OF HEALTH EFFECTS AND SYMPTOMS OF MICROBIALLY RELATED ILLNESSES IN JUICE—Continued

Hazard	Severity	Functional Status Code[1]	Symptom/Problem Complex Code[2]
	Severe	NA	NA

[1] Functional Status Codes are described in Table 4.
[2] Symptom/Problem Complex Codes are described in Table 5.
[3] The disutilities for two functional status codes were taken for severe cases of *E. coli* O157:H7 because functional status varies among severe cases of this hazard.
[4] Functional Status Code varies, Ref. 10.

In Table 4, the last column, ''Level of Disutility,'' represents the degree of departure from perfect functionality. Thus, a person would be functioning at about half capacity if the level was .5 and would be even more diminished at .75. Code L42 is used whenever the mobility, physical activity, and social activity conditions apply and a person is experiencing a symptom described in Table 5. Code L43 is used whenever the mobility, physical activity, and social activity conditions apply and a person is experiencing no symptoms. In Table 5, ''Level of Disutility'' refers to the amount of pain and suffering such that .03 would be minor pain and suffering relative to .3.

TABLE 4.—DESCRIPTION OF FUNCTIONAL STATUS CODES[1]

Function Status Levels	Mobility	Physical Activity	Social Activity	Level of Disutility
L1	In special care unit	In bed or chair	Had help with self-care	.5626
L6	In hospital	In bed or chair	Had help with self-care	.5301
L19	In house	Walked with physical limitations	Performed self-care but not work, school, or housework	.4176
L20	In house	Walked with physical limitations	Limited in work, school, or housework	.4448
L23	In house	Walked without physical limitations	Performed self-care, but not work, school, or housework	.3512
L31	Did not drive, needed help with transportation	Walked without physical limitations	Limited in work, school, or housework	.4087
L35	Drove car and used transportation without help	Walked with physical limitations	Limited in work, school, or housework	.3980
L41	Drove car and used transportation without help	Walked without physical limitations	Did work, school, or housework, but other activities limited	.3145
L42	Drove car and used transportation without help	Walked without physical limitations	Did work, school, or household, and other activities	.2567
L43	Drove car and used transportation without help	Walked without physical limitations	Did work, school, or household, and other activities	.0000

[1] Ref. 4.

TABLE 5.—DESCRIPTION OF SYMPTOM/PROBLEM COMPLEX CODES[1]

Symptom/Problem Complex	Description	Level of Disutility
8	Itching, bleeding or pain in rectum	.0379
9	Pain in chest, stomach, side, back, or hips	.0382
12	Sick or upset stomach, vomiting, or diarrhea (watery bowel movements)	.0065
13	Fever chills with aching all over and vomiting or diarrhea	.0722
16	Headache, dizziness, or ringing in ears	.0131
19	Pain, stiffness, numbness, or discomfort of neck, hands, feet, arms, legs ankles, or several joints together	.0344
29	General tiredness, weakness, or weight loss	.0027
32	Loss of consciousness such as seizures (fits), fainting, or coma (out cold or knocked out)	.1507

[1] Ref. 4, p. D–14.

3. Utility Losses From Microbial Hazards in Juice

The ''Functional Status Code'' translates into values of disutility given in the ''Functional Disutility'' column in Table 6. The symptom/problem complex code translates into values of disutility given in the ''Symptom/Problem Disutility'' column in Table 6. The ''Total Disutility'' column is the sum of the ''Functional Disutility'' and the ''Symptom/Problem Disutility'' columns. The ''Utility Losses for Survivors'' column is derived by multiplying the total disutility per day by the number of days that symptoms of the illness persists. This gives the utility loss for survivors in terms of the number of quality adjusted life days (QALD's) for each case of the categories of severity for each hazard.[6] FDA requests comment on this estimation of utility loss.

[6] A QALD is a day of perfect health.

TABLE 6.—UTILITY LOSSES FROM MICROBIAL HAZARDS IN JUICE

Hazard	Severity	Functional Disutility (per day)	Symptom/Problem Disutility (per day)	Total Disutility (per day)	Utility Losses for Survivors (QALD's)
E. coli O157:H7					
	Mild	.4448	.1193	.5641	2.8
	Moderate	.4176	.1668	.5844	5.3
	Severe-acute	.5464	.3175	.8639	27.8
	Severe-chronic	.4087	.0382	.4469	11,907.7
Salmonella (non *typhi*)					
	Mild	.4448	.0814	.5262	1.1
	Moderate	.4448	.0814	.5262	2.6
	Severe	.5301	.0945	.6246	10.6
	Reactive arthritis-short term	.3980	.0344	.4324	10.8
	Reactive arthritis-long term	.2582	.0280	.2862	5,223.2
B. cereus					
	Mild	.4176	.0814	.4990	.4
	Moderate	.4176	.0814	.4990	.5
	Severe	0	0	0	0

4. Value of Losses From Microbial Hazards in Juice

FDA values a QALD at $630. This value derives from the statistical estimate of a unit-risk reduction (commonly referred to as the value of a statistical life (VSL)) which the Department of Health and Human Services assigns the value of $5 million. Using $5 million for a full lifetime yields a value for a quality adjusted life year (QALY) of approximately $230,000, when discounted at 7 percent. (A QALY is the estimated value of a year spent in perfect health. These values are discounted to reflect time preferences for investments in health. That is, as with any other commodity, people have a stronger preference for good health now than they have for good health in the future. Costs or benefits realized in the future are ''discounted'' to make them comparable to today. Essentially, discounting is the inverse of the interest rate. Thus, if a benefit of $1.10 were to be realized 1 year in the future, this would be equivalent, at approximately a 10 percent discount rate, to a benefit of $1 realized today. This is the reverse of saying that $1 invested today at a 10 percent annual interest rate is worth $1.10 1 year from now.) Dividing this value by 365 days per year yields a value for a QALD of approximately $630. The ''Value of Utility Losses for Survivors'' column in Table 7 comes from multiplying the number of QALD's lost due to the illness (see ''Utility Losses for Survivors'' in Table 6) by the value of a QALD, $630. This represents the value of pain and mobility losses that individuals experience. Additionally, there are the societal costs of medical treatment. These costs are shared generally between insurance companies and individuals. They include all aspects of medical expenses (e.g., physician visits, laboratory tests, prescriptions and therapies, hospital stays). These are estimated in the ''Medical Costs'' column in Table 7 (Ref. 2–3, pp. 19 and 40 and Ref. 10). The ''Value of Losses per Case'' column in Table 7 is the sum of the ''Value of Utility Losses for Survivors'' column and the ''Medical Costs'' column for the categories of severity for each hazard. FDA requests comment on these valuations.

TABLE 7.—VALUE OF LOSSES FROM MICROBIAL HAZARDS IN JUICE

Hazard	Severity	Value of Utility Losses for Survivors (QALD=$630)	Medical Costs	Value of Losses per Case (VSL=$5,000,000) (QALD=$630)
E. coli O157:H7				
	Mild	$1,800	$0[1]	$2,000
	Moderate	$3,300	$200[1]	$4,000
	Severe-acute	$17,200	$16,000[2]	$33,000
	Severe-chronic	$995,700	$225,000[3]	$1,221,000
	Death	NA	NA	$5,000,000
Salmonella (non *typhi*)				
	Mild	$700	$200[4]	$1,000
	Moderate	$1,600	$800[4]	$2,000
	Severe	$6,700	$9,100[4]	$16,000
	Reactive arthritis-short term	$6,800	$100[5]	$7,000
	Reactive arthritis-long term	$970,000[5]	$5,860[5]	$976,000
	Death	NA	NA	$5,000,000
B. cereus				
	Mild	$300	$0[6]	$300
	Moderate	$300	$100[6]	$400
	Severe	$0	$0	$0

TABLE 7.—VALUE OF LOSSES FROM MICROBIAL HAZARDS IN JUICE—Continued

Hazard	Severity	Value of Utility Losses for Survivors (QALD=$630)	Medical Costs	Value of Losses per Case (VSL=$5,000,000) (QALD=$630)
	Death	NA	NA	$5,000,000

[1] Ref. 2–3, p. 40.
[2] Explained in Table 8.
[3] Recalculated from data in Buzby et al., pp. 41–45 in order to arrive at the present value of the cost per case using a 7 percent discount rate.
[4] Buzby et al., pp. 18–19. Mild Salmonella medical costs are recalculated from data in Cohen, M. L. et al. so as not to include productivity in medical costs.
[5] Ref. 10.
[6] The medical cost estimates for *B. cereus* were made by FDA for this analysis. The extremely brief duration of mild cases suggests that there would be no medical costs for this level of severity. For moderate cases one visit to a doctor with medical tests are estimated to cost approximately $100.

TABLE 8.—MEDICAL COSTS FOR SEVERE-ACUTE CASES ASSOCIATED WITH *E. coli* O157:H7[1]

Factors	Acute Hemorrhagic Colitis	Acute HUS	Average Severe-Acute Case
Percent of Severe Cases	80%	20%	
Present Value per Case	$11,000	$36,000	
Weighted Present Value per Case	$8,800	$7,200	$16,000

[1] Ref. 2–3, p. 40.

5. Distribution of the Reported Cases per Year for Microbial Hazards in Juice

Table 9 estimates the number of cases associated with each hazard by severity. The ''Average Total No. of Cases Reported per Year'' column represents the average number of reported cases for each hazard from 1992 through 1996. Cases for each hazard are divided among the four categories of severity according to the percentages described in Table 8. Only those reported cases associated with commercially-produced juices sold in interstate commerce as beverages or used as ingredients in beverages are included in the averages presented.

TABLE 9.—DISTRIBUTION OF THE REPORTED CASES PER YEAR FOR MICROBIAL HAZARDS IN JUICE

Hazard	Severity	Percent	Average No. of Cases Reported per Year
	Mild	50	8
	Moderate	32	5
	Severe-acute	18	3
	Severe-chronic	2	.3
	Death	1	.2
E. coli O157:H7	Total cases		16[1]
	Mild	65	8
	Moderate	30	4
	Severe	5	1
	Reactive arthritis-short term	2	.2
	Reactive arthritis-long term	5	1
	Death	.1	.01
Salmonella (non *typhi*)	Total cases		12
	Mild	99	17
	Moderate	1	.2
	Severe	0	0
	Death	0	0
B. cereus	Total cases		17

[1] Total cases per pathogen are accurate. The sum of the number of cases for all levels of severity per pathogen may not equal the total number of cases per pathogen due to rounding.

6. Estimates of Factors Needed to Offset Underreporting of Foodborne Illness

The cases reported in column 4 in Table 10 are the lower bound of the likely total number of these cases. The total number of foodborne illness is much greater than those numbers reported to the Centers for Disease Control and Prevention (CDC) for several reasons. First, individuals who become ill do not always go to doctors. This is particularly true for milder cases of foodborne disease. Obviously, if people do not go to health care professionals, the illnesses will not be captured in any data base and will not be picked up by CDC. Second, even when people go to health care professionals, they are not necessarily diagnosed as having foodborne disease as the symptoms for many types of

foodborne disease are common to influenza and other diseases. There is often little incentive to culture stools to definitively identify a pathogen if the disease is thought to be of short duration and not requiring treatment. Even where a pathogen is identified, there is even less incentive to identify the food or other vehicle which carried it. Third, even when a correct diagnosis is made, State and local health professionals do not always report these cases upwards, particularly going as far as CDC. Again, milder cases are less likely to be reported than more severe cases.[7] To complicate matters, the rate of under reporting is not observable, and, even if it were known in any 1 year, it may fluctuate dramatically from year to year. Nevertheless, in order to compensate for the rate of under reporting, the number of known cases associated with a hazard (i.e., reported to CDC) is multiplied by factors which are estimated to account for underreporting.

In *Foodborne Pathogens: Risks and Consequences* (the CAST Report) there are two estimates given of the actual number of foodborne illnesses: One estimate made by Bennett et al., and one made by Todd (Ref. 6, p. 46). Both Bennett et al. and Todd estimate the total number of cases and the total number of deaths for each hazard. By dividing Bennett's et al. and Todd's estimates of the actual number of cases and deaths by the number of reported cases and deaths (Ref. 6, p. 42), the respective implicit factors needed to correct for underreporting of these categories for each hazard are derived. Based on these correction factors, FDA has estimated correction factors for each category of severity. The agency has taken the correction factor for the number of cases as the correction factor for mild cases and the correction factor for the number of deaths as the correction factor for severe cases. For moderate cases, the agency has interpolated between the factors for mild and severe cases. *E. coli* O157:H7 was not a recognized food-safety hazard at the time that Bennett's et al. work was done. For a more complete description of how these estimates were derived see the Appendix attached to this document (Ref. 9).

In Table 10, the third column, ''Estimate of Underreporting Correction Factor (Bennett),'' and the fifth column, ''Estimate of Underreporting Correction Factor (FDA based on Todd),'' give the exact implicit correction factors that can be derived from the work of Bennett and Todd et al. The fourth column, ''Estimate of Underreporting Correction Factor (FDA based on Bennett),'' and the sixth column, ''Estimate of Underreporting Correction Factor (FDA based on Todd),'' give FDA's interpolations of the work of Bennett and Todd et al. for each of the identified categories of severity. In general, each researcher's estimate of the underreporting correction factor for total cases was used as the estimate for mild cases, and each researcher's estimate of the underreporting correction factor for deaths was used as the estimate for deaths and severe cases. FDA interpolated between each researcher's estimates of underreporting for total cases and deaths to derive under reporting rates for moderate cases. FDA requests comment on these estimates of underreporting.

TABLE 10.—ESTIMATES OF FACTORS NEEDED TO OFFSET UNDERREPORTING OF FOODBORNE ILLNESS

Hazard	Severity	Estimate of Underreporting Correction Factor (Bennett)	Estimate of Underreporting Correction Factor (FDA based on Bennett)	Estimate of Underreporting Correction Factor (Todd)	Estimate of Underreporting Correction Factor (FDA based on Todd)
	Mild				195
	Moderate				20
	Severe				7
	Death			7	7
E. coli O157:H7	Total cases	ND[1]		195	
	Mild		307		474
	Moderate		307		45
	Severe		246		4
	Reactive arthritis-short term		307		474
	Reactive arthritis-long term		307		474
	Death	246	246	4	4
Salmonella (non *typhi*)	Total cases	307		474	
	Mild		96		1,615
	Moderate		96		1,615
	Severe	NA	NA	NA	NA
	Death	NA	NA	NA	NA
B. cereus	Total cases	96		1,615	

7. Estimates of Juice-Associated Cases per Year

In Table 11, FDA has estimated ranges of the likely annual number of cases that occur for each of the four pathogens studied. The column ''Estimate of Actual No. of Juice Associated Cases per Year (FDA based on Bennett)'' in Table 11 is derived by multiplying the ''Average Total No. of Reported Cases per Year'' column in Table 9 by the ''Estimate of Underreporting Correction Factor (FDA based on Bennett)'' column in Table 11. The column ''Estimate of Actual No. of Juice Associated Cases per Year (FDA based on Todd)'' in Table 11 is calculated in a similar manner.

[1] The CAST Report expands these three categories of reasons that a case of illness may not be recognized as foodborne into six reasons (Ref. 6).

TABLE 11.—ESTIMATES OF JUICE-ASSOCIATED CASES PER YEAR

Hazard	Severity	Estimate of Under-reporting Correction Factor (FDA based on Bennett)	Estimate of Under-reporting Correction Factor (FDA based on Todd)	Estimate of Actual No. of Juice-Associated Cases per Year (FDA based on Bennett)	Estimate of Actual No. of Juice-Associated Cases per Year (FDA based on Todd)
	Mild	ND	195	ND	1,560
	Moderate	ND	20	ND	100
	Severe-acute	ND	7	ND	20
	Severe-chronic	ND	7	ND	2
	Death	ND	7	ND	1
E. coli O157:H7	Total cases			ND	1,700
	Mild	307	474	2,460	3,790
	Moderate	307	45	1,230	180
	Severe	246	4	150	2
	Reactive arthritis-short term	307	474	60	100
	Reactive arthritis-long term	307	474	180	280
	Death	246	4	2	.04
Salmonella (non *typhi*)	Total cases			3,800	4,000
	Mild	96	1,615	160	2,750
	Moderate	96	1,615	2	30
	Severe	0	0	0	0
	Death	0	0	0	0
B. cereus	Total cases			200	2,800

8. Percent of Cases Preventable by HACCP Proposal

In general, most pathogens will be eliminated when juice is heat-treated. For example, *E. coli* O157:H7, and *Salmonella* should all be completely eliminated from juice by standard methods of flash pasteurization (absent extraordinarily high counts, detrimental human intervention, or equipment failure). However, hazards associated with *B. cereus* will not necessarily be eliminated by heat treatment. This bacterium forms spores which are more difficult to kill by heat. After heat treatment, if the spores survive, they may grow out and produce a toxin which causes illness. Ideally, the best way to reduce illness associated with *B. cereus* is by killing the bacterium in its nonspore state before any toxin has been produced. For most types of heat-treated juice, there is a small probability that the heat treatment will take place when *B. cereus* is in its nonspore state. To the extent that processors adopt controls for these hazards other than flash pasteurization which are less effective, the percentage of cases prevented may be smaller than those estimated here. FDA requests comment on these estimates. Based on information from USAA, FDA estimates that the exemption from the HACCP rule for retailers and small retail processors will affect 14 percent of the volume of unpasteurized juice. Therefore, the agency estimates that though pathogen controls may be 100 percent effective in controlling some hazards, such controls will only prevent 86 percent of the cases of illness from these hazards.

TABLE 12.—PERCENT OF CASES PREVENTABLE BY HACCP PROPOSAL

Hazard	Percent of Cases Preventable by HACCP Proposal
E. coli O157:H7	86

TABLE 12.—PERCENT OF CASES PREVENTABLE BY HACCP PROPOSAL—Continued

Hazard	Percent of Cases Preventable by HACCP Proposal
Salmonella (non *typhi*)	86
B. cereus	9

9. Estimates of Annual Benefits for HACCP Proposal

The total benefits for the categories of severity for each hazard are derived by multiplying the percentage of cases preventable by the HACCP proposal by the estimates of the number of actual cases. The sum of those benefits for each hazard is the total benefits of the HACCP proposal for pathogen control. Table 13 gives the estimate of benefits for each hazard using each source of information on the appropriate correction factor for underreporting.

TABLE 13.—ESTIMATES OF ANNUAL BENEFITS FOR HACCP PROPOSAL

Hazard	Severity	FDA Estimate of Annual Benefits Based on Bennett	FDA Estimate of Annual Benefits Based on Todd
	Mild		$2,680,000
	Moderate		$360,000
	Severe-acute		$660,000
	Severe-chronic		$2,442,000
	Death		$5,000,000
E. coli O157:H7	Total		$11,142,000
	Mild	$2,120,000	$3,260,000

TABLE 13.—ESTIMATES OF ANNUAL BENEFITS FOR HACCP PROPOSAL—Continued

Hazard	Severity	FDA Estimate of Annual Benefits Based on Bennett	FDA Estimate of Annual Benefits Based on Todd
	Moderate	$2,120,000	$300,000
	Severe	$2,080,000	$32,000
	Reactive arthritis-short term	$350,000	$630,000
	Reactive arthritis-long term	$146,400,000	$234,240,000
	Death	$10,000,000	$200,000
Salmonella (non *typhi*)	Total	$163,070,000	$238,662,000
	Mild	$42,000	$711,000
	Moderate	$1,000	$12,000
	Severe	0	0
	Death	0	0
B. cereus	Total	$43,000	$725,000

Table 14 presents a range of estimates of annual benefits based on the estimates in Table 13. The low and high estimates do not represent lower and upper bounds of benefits, but only a range of potentially likely estimates.

TABLE 14.—RANGE ESTIMATES OF ANNUAL MICROBIALLY RELATED BENEFITS FOR HACCP PROPOSAL

Hazard	Low Estimate of Annual Benefits	High Estimate of Annual Benefits
E. coli O157:H7	$11,142,000	$11,142,000
Salmonella (non *typhi*)[1]	$163,070,000	$238,662,000
B. cereus[1]	$43,000	$725,000
Totals	$174,000,000	$251,000,000

[1] Ranges for these two pathogens are taken from two different estimates that exist in the public health literature. The estimates for the other pathogen was made by FDA, alone.

10. Percent of Cases Preventable by Labeling Proposal

FDA does not have direct estimates of the effects of a warning label on the incidence of illness from juice consumption. FDA indirectly estimates the effects by estimating how warning labels will change consumption, assuming that changes in the number of illnesses are proportional to changes in consumption. FDA believes that the labeling rule will cause a reduction in the consumption of unpasteurized juice, but the size of the reduction is uncertain. As a likely value, FDA estimates that consumption and illnesses will decline by 5 percent in response to the warning label. The 5 percent reduction is the estimated effect on cooking practices of the USDA meat safe handling label, as found in a recent survey (Ref. 11). However, there are some dissimilarities between the meat and juice labels, most particularly that the juice label is targeted at sensitive consumers. If, for example, parents redirect children away from nonheat-treated juice, then consumption and illness will decline by 16 percent, which is the proportion of apple cider consumed by children under the age of 6 (Ref. 12). This estimate embodies the assumptions that cider consumption is a good proxy for unpasteurized juice consumption, and that parents will not let their children consume unpasteurized juices.

11. Estimates of Annual Benefits for Labeling Proposal

Table 11 shows FDA's estimate that there are approximately 5,600 cases of foodborne illness associated with commercially processed, package juice produced by nonretail establishments. In addition to these cases, an average of 6 cases annually of *Cryptosporidium parvum* have been associated with commercially processed, packaged juice produced by retail establishments exempted from the HACCP rule. Table 15 shows the agency's estimate of the actual number of cases per year by severity.

TABLE 15.—ESTIMATES OF JUICE-ASSOCIATED *C. parvum* CASES PER YEAR

Severity	Average No. of Cases Reported per Year (1992–1996)	FDA Estimate of Underreporting Correction Factor[1]	FDA Estimate of Actual No. of Juice-Associated Cases per Year
Mild	5	100	500
Moderate	1	10	10
Severe	.06	5	.3
Death	.001	5	.005
Total	6		500

[1]Because *C. parvum* was not a recognized food safety hazard at the time that Bennett et al. and Todd's work was done, FDA has made its own estimates of the factors needed to correct for underreporting of this hazard.

Table 16 gives the agency's estimate of the value of the loss per case of *C. parvum*.

TABLE 16.—ESTIMATE OF VALUE OF LOSSES ASSOCIATED WITH CASE OF *C. parvum*

Severity	Percent	Duration of Illness (in days)	Function Status Code[1]	Symptom/Problem Complex Code[2]	Total Disutility (per day)	Utility Losses for Survivors (QALD's)	Value of Utility Losses for Survivors (QALD=$630)	Medical Costs	Value of Losses per Case (VSL=$5,000,000) (QALD=$630)
Mild	90	9	L41	12, 13, 29	.3959	3.6	2,300	$0[3]	$2,000
Moderate	9	17	L41	12, 13, 29	.3959	6.7	$4,200	$400[3]	$5,000
Severe	1	24	L6	12, 13, 29	.6115	14.7	$9,300	$8,300[4]	$18,000
Death	.02						NA	NA	$5,000,000

[1]Functional Status Codes are described in Table 4.
[2]Symptom/Problem Complex Codes are described in Table 5.
[3]Medical Costs for mild and moderate cases of *C. parvum* were calculated by multiplying the per day medical costs for *E. coli* 0157:H7 for these levels of severity by the duration of illness of *C. parvum*. The symptoms of *C. parvum* for these levels of severity are similar to those of *E. coli* 0157:H7.
[4]Medical Costs for severe cases of *C. parvum* were calculated by multiplying the per day medical costs for severe cases of acute hemorrhagic colitis by the duration of illness of *C. parvum*. The implicit assumption is that the medical costs for acute hemorrhagic colitis (bloody diarrhea) are equivalent to the medical costs for watery diarrhea associated with *C. parvum*.

The labeling rule is expected to prevent some cases of foodborne illness as people avoid juice that is labeled. Because *B. cereus* is, in general, not disproportionately associated with minimally processed juice, cases of *B. cereus* are not expected to be prevented by the labeling. However, to the extent that the label is effective and to the extent of the volume of juice that is labeled, the labeling rule will reduce the number of cases associated with *E. coli* 0157:H7, *Salmonella* and *C. parvum*.

Combining the estimates of the number of illnesses in Tables 11 and 15, the total number of estimated cases associated with minimally processed juice for these 3 hazards is 6,100 per year associated with consumption of the 70 million gallons of minimally processed juice produced annually. FDA has estimated that 14 percent of minimally processed juice (10 million gallons) will be exempt from the HACCP rule but will be covered by the labeling rule. Therefore, the number of illnesses that may be associated with this volume of juice (10 million gallons) will be exempt from the HACCP rule but will be covered by the labeling rule. Therefore, the number of illnesses which may be associated with this volume of juice (10 million gallons) is approximately 900 and 5,200 illnesses are associated with minimally processed juice covered by the HACCP rule.

As stated earlier, FDA estimates that consumption of labeled, minimally processed juice will decline by 5 percent in response to the warning label. This leads to the conclusion that the labeling rule is expected to prevent approximately 50 illnesses annually (900 x .05). If juice consumption decreases by as much as 16 percent in response to the warning label, then the labeling rule may prevent as many as 140 illnesses per year.

The value of this reduction in illness depends on the type of cases prevented. FDA assumes that these cases will be distributed according to the share of illnesses associated with each of these hazards. Table 17 shows the expected distribution of cases prevented by labeling across the hazards and severities.

TABLE 17.—DISTRIBUTION OF CASES PREVENTED BY LABELING PROPOSAL

Hazard	Severity	Low Estimate of Actual No. of Juice-Associated Cases per Year	High Estimate of Actual No. of Juice-Associated Cases per Year	Low Estimate of No. of Cases Prevented by a 5% Consumer Response to Labeling	High Estimate of No. of Cases Prevented by a 5% Consumer Response to Labeling	Low Estimate of No. of Cases Prevented by a 16% Consumer Response to Labeling	High Estimate of No. of Cases Prevented by a 16% Consumer Response to Labeling
	Mild	1,560	1,560	13	13	36	35
	Moderate	100	100	1	1	2	2
	Severe-acute	20	20	.2	.2	.5	.5
	Severe-chronic	2	2	.02	.02	.05	.05
	Death	1	1	.008	.008	.02	.02
E. coli 0157:H7	Total	1,700	1,700	14	14	39	38
	Mild	2,460	3,790	20	31	58	87
	Moderate	1,230	180	10	1	29	4
	Severe	150	2	1	.02	4	.05
	Reactive arthritis-short term	60	100	.5	.8	1	2
	Reactive arthritis-long term	180	280	1	2	4	6
	Death	2	.04	.02	.0003	.05	.0009
Salmonella (non typhi)	Total	3,800	4,000	32	32	90	91
	Mild	500	500	4	4	11	11
	Moderate	10	10	.08	.08	.2	.2
	Severe	.3	.3	.002	.002	.006	.006
	Death	.005	.005	.00004	.00004	.0001	.0001
C. parvum	Total	500	500	4	4	11	11
Total		6,000	6,200	50	50	140	140

TABLE 18.—VALUE OF LOSSES PREVENTED BY THE LABELING PROPOSAL

Hazard	Severity	Low Estimate of Value of Losses Prevented by a 5% Consumer Response to Labeling	High Estimate of Value of Losses Prevented by a 5% Consumer Response to Labeling	Low Estimate of Value of Losses Prevented by a 16% Consumer Response to Labeling	High Estimate of Value of Losses Prevented by a 16% Consumer Response to Labeling
	Mild	26,000	26,000	72,000	70,000
	Moderate	4,000	4,000	8,000	8,000
	Severe-acute	7,000	7,000	17,000	17,000
	Severe-chronic	24,000	24,000	61,000	61,000
	Death	40,000	40,000	100,000	100,000
E. coli 0157:H7	Total	101,000	101,000	258,000	258,000
	Mild	20,000	31,000	58,000	87,000
	Moderate	20,000	2,000	58,000	8,000
	Severe	16,000	300	64,000	1,000
	Reactive arthritis-short term	4,000	6,000	7,000	14,000
	Reactive arthritis-long term	976,000	1,952,000	3,904,000	5,856,000
	Death	100,000	2,000	250,000	5,000
Salmonella (non typhi)	Total	1,136,000	1,993,000	4,341,000	5,971,000
	Mild	8,000	8,000	22,000	22,000
	Moderate	400	400	1,000	1,000
	Severe	0	0	100	100
	Death	200	200	500	500
C. parvum	Total	9,000	9,000	24,000	24,000
Total		1,000,000	2,000,000	5,000,000	6,000,000

12. Pesticide Residues

Tolerances for pesticides in foods are established by the Environmental Protection Agency (EPA) and enforced by FDA. FDA collects samples for both surveillance and compliance purposes. Since the incidence of violative pesticide residues in fruit and vegetable juices is relatively low, few compliance samples are taken.

This discussion pertains to surveillance samples of fruit and vegetable juices from 1991 through 1997 (see Table 15). The lab classification scheme used for pesticide residues is:

1 = in compliance;

2 = not in compliance, but not of regulatory concern; and

3 = not in compliance, and of regulatory concern.

The class 2 and 3 violative sample data are summarized in Table 15. Of the 1,196 surveillance samples of juice taken and analyzed during this period, only three (approximately one quarter of one percent) were class 3 violative. One was apple cider and the other two were apple juice, and the violative pesticide residue was acephate in each case. There were also five class 2 violations, in which trace quantities of a pesticide with no tolerance (i.e., the pesticide was not approved for use in the commodity) were found. The products with class 2 violations were grape juice, watermelon juice concentrate, strawberry/nectarine juice (2 samples), and apple juice concentrate; the pesticides were chlorpyrifos, acephate, and methamidophos.

Pesticides present some potential chronic risks to humans at very low levels of exposure. There is a small background risk associated even with nonviolative pesticide residues and, in the case of products with violative levels, an added risk from the violative residues. (Violative residues are residues above tolerance or residues of pesticides with no tolerance.)

TABLE 19.—VIOLATIVE PESTICIDE RESIDUES IN FRUIT AND VEGETABLE JUICES, 1991 THROUGH 1997

Commodity	Fiscal Year	Pesticide	Amount Found, ppm	Tolerance, ppm	Class Violation
Grape juice	1993	Chlorpyrifos	Trace	None	2
Apple cider	1995	Acephate	0.075	None	3
Apple juice	1995	Acephate	0.052	None	3
Apple juice	1995	Acephate	0.040	None	3
Watermelon juice, concentrate	1995	Acephate	Trace	None	2
Strawberry/nectarine juice	1996	Methamidophos	Trace	None	2
Strawberry/nectarine juice	1996	Methamidophos	Trace	None	2
Apple juice, concentrate	1997	Methamidophos	Trace	None	2

There are two potential benefits associated with the regulation of pesticides: (1) Decreases in cancer and other illness caused by chronic consumption of pesticide residues and, (2) social benefits associated with reductions in the costs of recapturing firm goodwill. The U.S. EPA is responsible for determining the benefits of reducing exposure to pesticide residues and, it is assumed, that the health benefits of the enforcement actions proposed here are already accounted for when regulatory tolerances are established. As to the

latter benefit, when firms have products with violative residues either over tolerance for legal pesticides or any residue of an illegal pesticide and a recall of the violative product becomes publicly known, the sales of those firms are reduced, at least temporarily. Because other firms will step in to supply the product, that loss of sales alone does not constitute a social cost. However, it is likely that real resources will be expended to recapture the lost ''goodwill'' that would be in addition to the real expenditures made to actually recall the product. FDA cannot quantify the cost savings that will occur because of more vigilant monitoring of pesticide residues by firms under a HACCP rule.

C. Other, Nonquantified Benefits

1. Firm Efficiency

The principle benefits from HACCP reported by the pilot firms are more effective and efficient operations, a higher level of confidence in the safety of the product, and greater customer satisfaction. The pilot firms attributed these benefits to HACCP because of the following results.

(1) Training makes the employees more aware of safety and needed control measures, and empowers employees to prevent problems and respond properly when deviations occur. Improvement in employee performance was perhaps the most significant benefit from HACCP expressed to FDA by the pilot firms. One firm reported that ''due to increased HACCP awareness, employees have been instrumental in designing new processes/procedures for monitoring and control.'' The firm gave an example of a processing step that was changed to reduce the likelihood of occurrence of a physical hazard. FDA is unable to estimate the societal cost savings in terms of reduced product costs which will, ultimately, affect the cost of implementing HACCP.

(2) SOP's and other documented procedures enable employees to implement their tasks more consistently and effectively, and result in smoother operations.

(3) Prerequisite programs and incoming ingredient controls prevent hazards from being introduced into the process; continuous monitoring reveals problems quickly and enables prompt correction and continuation of production with less waste.

(4) Recordkeeping and review makes employees more accountable and conscientious about safety.

(5) Validation and verification activities provide management with greater control over their operations and documentation of the safety of their product.

Perhaps the most significant benefit in terms of firm efficiency will be cost savings from greater awareness by firms of violative product runs, and the resulting increase in response to such violative runs. Although the benefits of formal recalls have already been accounted for, many pilot plant managers suggested that the continuous monitoring required by HACCP enabled them to decrease the amount of waste associated with production-line problems. For example, one manufacturer noted that glass breakage was a constant problem on the line and that, prior to HACCP, almost an entire lot would have to be discarded because the manager could not be sure exactly when a problem had started. With continuous HACCP monitoring, problems were caught more quickly and the problem corrected more promptly, thereby minimizing the amount of lost product.

The cost savings may be substantial from this source of benefits but FDA is unable to quantify them. FDA requests comments on these and other potential benefits.

2. Increased Shelf Life

Nonheat-treated juices have a limited shelf life. Heat-treated juices have longer shelf lives. Depending upon temperature used, increases of 7 days or more have been reported. Longer shelf life allows more flexibility in the conditions of distribution and sale of products. The agency requests comments on how this potential benefit may be quantified.

D. Summary of Benefits

Table 20 summarizes the benefits of these two rules.

TABLE 20.—BENEFITS OF JUICE PROPOSALS

Type of Benefit	Description	Annual Value
Enforcement: Import Detentions	Reduced waste and Federal activity from detaining violative juice imports	$175,000
Enforcement:Product Recalls	Reduced numbers of domestic recalls of violative juice products	$1,500,000
Health Benefits: HACCP	Reduced illness and death from controlling pathogens in juice	$174 to 251 million
Health Benefits: Labeling	Reduced illness and death from avoidance of minimally processed juice	$1 to $6 million
Health Benefits: Pesticides	Reduction of consumption of violative pesticide residues in juice and social losses from lost goodwill	Not quantified but small
Other Benefits: Firm Efficiency	Some offsetting reductions in manufacturing costs due to increased worker productivity and less product waste	Not quantified but potentially large
Other Benefits: Increased Shelf Life	Product Shelf life may be increased for products achieving a 5-log reduction of pathogens	Not quantified but potentially large
Total Quantified Benefits		$180 to 260 million

VI. Costs

A. General Industry Information Used Throughout This Analysis

The costs of these rules have been estimated by analyzing the costs for each proposed requirement on a per-plant basis and multiplying these costs by the number of plants affected by each requirement. Cost per plant will vary by current practice, product, and size. In order to determine the number of plants covered, the analysis will first analyze coverage qualitatively.

1. Types of Plants Covered

The labeling rule and the HACCP rule do not equally affect an identical subset of the food industry.

2. HACCP Rule Coverage

For the purpose of this rule, FDA has tentatively decided that retailers will include processors who are very small businesses and who make juice on their premises and directly sell juice or juice products to consumers and other retailers provided that retail sales of juice and juice products do not exceed 40,000 gallons per year. The HACCP rule covers all processors of juice except those who are retailers. Retailers may include grocery stores, supermarkets, farms, roadside stands, restaurants and eating places.

3. Labeling Rule Coverage

The labeling rule covers processors and retailers of packaged minimally processed juice. The labeling rule is also applicable to packaged beverages that have not received further processing to control microbial hazards and that contain minimally processed juice. Such beverages include diluted juice beverages, ''smoothies,'' sports drinks, flavored bottled waters, and carbonated beverages that contain juice that was not processed to control pathogens.

Table 21 provides examples of the types of products and processors covered and not covered by the two rules.

TABLE 21.—COVERAGE OF JUICE PROPOSALS

Processor Type	Covered by Labeling Rule	Covered by HACCP Rule[3]
Processors of packaged beverages sold as juice[1]	Yes	Yes
Processors of packaged purees sold as juice	Yes	Yes
Processors of juice used as an ingredient in a beverage (e.g., the cranberry juice in cranberry juice cocktail)	Yes	Yes
Processors of juice which retail the juice at a different location from which it is produced	Yes	Yes
Processors of beverage concentrates sold as juice	Yes	Yes
Processors of beverage bases of a fruit origin or other beverage bases including dried or powdered juice mixes[2]	Yes	Yes
Processors of packaged baby (infant and junior) fruit juices and drinks	Yes	Yes
Processors of juice that ship to a different location (e.g., the juice processing plant owned by a supermarket chain that then ships the juice to the chain's stores or very small processors that sell juice from their own roadside stand and to other retailers)	Yes	Yes
Retailers of packaged juice processed by other establishments (e.g., supermarkets, restaurants and roadside stands that sell juice produced by another processor) Note: the juice sold by these retailers is covered by the HACCP rule but the retailer is not covered by the HACCP rule.	Yes	No
Processors of packaged juice that do not ship juice to different locations but retail the entire production on the premises (e.g., supermarkets, and roadside stands that produce juice at the point of sale)	Yes	No
Processors of beverages that include juice as an ingredient but which do not produce the juice itself	Yes	No
Retailers of juice processed for immediate consumption	No	No
Processors of non-beverage products that include juice as an ingredient	No	No
Processors of hard cider or other alcoholic beverages	No	No
Processors of oils	No	No
Processors of purees not sold as beverages (e.g., tomato puree)	No	No
Processors of juices not sold as beverages (e.g., vinegar or borscht)	No	No
Processors of imitation juice flavorings	No	No
Processors of coffees, teas, or cocoa products	No	No

[1] Juice types are berry; citrus; core fruit; mixed fruit; pit fruit; subtropical and tropical fruit; vine fruit; other fruit; beans, peas and corn; fruits used as vegetables; leaf and stem vegetables; mixed vegetables; root and tuber vegetables; and other vegetables.

[2] Beverage bases of fruit origin are berry, citrus, core fruit, mixed fruit, pit fruit, subtropical and tropical fruit, vine fruit, and other fruit.

[3] A ''yes'' in this column applies only to processors producing in excess of 40,000 gallons of packaged juice per year. Very small businesses processing packaged juice, producing 40,000 gallons of juice or less annually are classified as retailers for the purpose of the HACCP rule and are therefore exempt from it.

4. Number of Establishments Covered

FDA's own Official Establishment Inventory (OEI, FDA's list of food establishments under its jurisdication) lists approximately 900 juice manufacturers. However, recent information from the U.S. Apple Association (USAA) indicates that there are about 1,800 apple juice plants, most of which are very small processors. A typical description of these very small processors is an apple grower who operates a small apple press and bottling operation on the same property. In general these processors market their products in more than one way. The channels of distribution include: Roadside stands owned by the processors and stands owned by others, farmers' markets, grocery stores, and restaurants. FDA has proposed to exempt retail establishments from the HACCP rule. For the purposes of this rule, the agency has tentatively decided that retailers will include very small businesses that make juice on their premises and whose total sales of juice and juice products do not exceed 40,000 gallons per year and who sell directly to consumers or directly to consumers and other retailers. Based on data supplied by the USAA, this exemption would exempt from the HACCP rule 80 percent of apple juice processors. (Ref. 13). Such an exemption would leave approximately 360 apple juice processors covered by both of these regulations, and all 1,800 would be covered by the labeling rule.

The OEI lists about 200 plants in the United States that produce core fruit (apple, crab apple, pear, quince, etc.) juice. If all of the 200 core fruit plants in the OEI are included in the USAA list and are not exempt, then there would still be an excess of 160 apple juice processing plants in the USAA list not exempt from the HACCP rule and an excess of 1,600 (1,800-2000) plants in the USAA list not exempt from the labeling rule. (Information from FDA's field inspections indicates that very few of these 160 plants will be exempted from the HACCP rule under the exemption for retailers of juice for immediate consumption. Almost none of the very small apple juice processing plants recently inspected by FDA retailed all of the juice that they produced at the same location that it was processed. See Table 21 for a description of the types of products and processors not covered.)

The agency is aware that there are also many very small orange juice processors who grow oranges and who also operate a juicing and bottling operation on the same property. However, the agency has no direct information on the number of such orange juice processors. The OEI lists about 300 plants in the United States that produce citrus fruit juice. In this analysis, the agency has assumed that there is an equivalent number (300) of very small processors who are not listed in the OEI. It is likely that the proportion of very small orange juice

processors to OEI citrus juice makers is lower than the proportion of very small apple juice processors to OEI apple juice makers because the growing region for oranges in the United States is far smaller than the region for growing apples.

FDA assumes for the purpose of this analysis, that 80 percent of these very small orange juice processors will be exempt from the HACCP rule based on their classification as retail establishments. This would leave 60 very small orange juice processors covered by both of these regulations, and all 300 covered by the labeling rule. FDA has assumed that there are no vegetable juice processors which are not in the OEI or which are not also very small processors of apple or orange juice as estimated above. FDA requests comments on these assumptions.

FDA has assumed that 5 percent (about 50 plants (900 x .05)) of all juice plants in the OEI would have implemented HACCP substantially in the form required by this regulation by the time that this proposed HACCP rule is finalized regardless of this regulatory action. Therefore, approximately a total of 1,070 plants (850 plants in the OEI plus 60 very small orange and 160 apple juice retailers) will be affected by the HACCP rule.

The labeling rule will cover retailers (roadside stands and grocery stores) of packaged minimally processed juice.

The agency does not have direct information on the number of supermarkets and grocery stores that produce and package at the point of sale and sell minimally processed juice. The agency believes that only a portion of chain supermarkets and grocery stores do so. Duns Market Identifier (DMI) lists approximately 9,400 chain supermarkets (SIC 54110101) and approximately 3,800 chain grocery stores (SIC 54119904) making a total of approximately 13,000 chain supermarkets and grocery stores. If 10 percent of these stores produce at the point of sale and sell packaged minimally processed juice, then approximately 1,300 chain grocery stores and supermarkets will be affected by the labeling rule. (In addition to these processors, there are other retailers that do not process juice but which offer for sale the juice produced by other processors, which should be labeled by the manufacturer.)

Due to publicity about the hazards associated with minimally processed juice, the agency believes that relatively few retailers are offering such products for sale. DMI lists approximately 3,100 independent supermarkets (SIC 54110103) and approximately 31,000 independent grocery stores (SIC 54119905) making a total of approximately 34,100 chain supermarkets and grocery stores. If 5 percent of these stores sell minimally processed packaged juice, then approximately 1,700 independent grocery stores and supermarkets will be affected by the labeling rule. The labeling rule will also affect roadside markets and stands that retail packaged minimally processed juice. For the purpose of this analysis, the agency assumes that there are 1,000 such roadside markets and stands. However, the assumptions that go into these calculations may be incorrect, and the agency specifically requests comments on them.

Table 22 shows the estimated number of establishments affected by each rule.

TABLE 22.—NUMBER OF PLANTS AFFECTED BY THE HACCP AND LABELING RULES

Plant Type	No. of Establishments Affected by HACCP Rule	No. of Establishments Affected by Labeling Rule
Juice manufacturers in the OEI	850	20[1]
Very small apple juice makers	160	1,600
Very small orange juice makers	60	300
Roadside retailers		1,000
Grocery stores and supermarkets processing and packaging at the point of sale		1,300
Total	1,070	4,220

[1] The number of juice manufacturers listed in the OEI affected by the labeling rule is small (20) because most of these manufacturers are already achieving a 5-log reduction. See Table 24.

5. Hourly Price of Labor

Throughout this analysis the hourly price of labor is taken to be approximately $13. This is estimated by taking the 1996 average hourly rural wage of $9.20 (Ref. 7) and increasing it by 40 percent (the average amount for benefit costs paid by employers) (Ref. 8), or $3.70 to account for such costs in addition to wages, such as Social Security, workers' compensation, unemployment insurance, paid leave, retirement and savings, health insurance, and supplemental pay.

6. Length of Production Period

The agency is aware that many juice processors operate on a seasonal basis. Information supplied by USAA indicates that 94 percent of the apple cider producers process only seasonally. The season for apple cider production runs primarily from September through December. The other 6 percent operate year round. Many other processors covered by the proposed HACCP rule (e.g., makers of beverage bases) may process year round. The agency has assumed that 50 percent of the 850 plants in the OEI plus all of the 220 very small juice makers affected by the HACCP rule produce seasonally. Table 23 shows the length of the production period for plants producing seasonally and year round.

TABLE 23.—PLANTS' PRODUCTION PERIOD

Production	Weeks of Operation per Year	Hours of Operation per Day	No. of Plants
Seasonal	16	12	645
Year Round	52	24	425
Total			1,070

B. Cost Estimates by Requirement

1. Costs have been estimated for the following sections of the labeling regulation:

(1) Signs or Placards (§ 101.17(f)(3)(i) (part 101 (21 CFR part 101))

(2) Container Labels (§ 101.17(f)(3)(ii))

2. Costs have been estimated for the following sections of the HACCP regulation:

(1) CGMP's (§ 120.5 (part 120 (21 CFR part 120))

(2) Prerequisite Program SOP's (§ 120.6)

(3) Hazard Analysis and HACCP Plan (§§ 120.7 and 120.8)

(4) Corrective Actions (§ 120.10)

(5) Validation and Verification (§ 120.11)

(6) Records (§ 120.12)

(7) Training (§ 120.13)

(8) Imports and Foreign Processors (§ 120.14)

1. Labeling Costs

This cost depends strongly upon producers' responses to the labeling requirements. Some producers may elect to comply early with the HACCP rule and avoid the warning labels or labeling. Others may choose to label until they are required to implement HACCP. Finally, some firms may choose not to produce juice products because they believe that either the cost of HACCP implementation or the negative effect on revenue generated by consumer response to labels may depress profits below a normal return for a substantial time period. Such producers will be better served by reinvesting their capital into more profitable ventures.

a. *Signs or placards (§ 101.17(f)(3)(i)).* The costs of signs and placards may be estimated by multiplying the number of establishments that must post placards by the cost per placard. As shown in Table 22 the agency estimates that the labeling rule covers approximately 4,220 plants. However, for the purpose of this analysis, the agency has assumed that all those processors that will at some point be required to implement HACCP will do so at the earliest possible date to avoid the warning labeling, or delay operation until they implement a 5-log pathogen reduction process.

The following analysis underlies this assumption. If displaying the warning can be avoided by beginning pasteurization (or an equivalent 5-log pathogen reduction process) sooner, some firms may marshal the resources to do so. FDA does not have data, however, that will allow it to predict how many firms will respond to this labeling regulation in this fashion. However, one way to examine this choice is examine the additional discounted costs of pasteurizing sooner. For example, if a small firm's cost of initiating pasteurization is about $18,000, with recurring costs of about $8,000, and the firm has an annual juice revenue of $200,000, then a total sales decline caused by the warning of 8 percent (a loss of approximately $16,000 discounted at a rate of 7 percent) or more spread over the course of 2 years (or approximately 4 percent for 2 years) would cause the firm to attempt to borrow the funds needed to initiate pasteurization 2 years early or to delay operation until it implements a 5-log pathogen reduction process. FDA's predictions of consumer reactions to the labeling (for the purposes of benefit estimations) are an expected loss of revenue of about 5 percent. Thus, there is a tentative conclusion that most firms that are not exempt from the HACCP rule will choose to implement a 5 log reduction in pathogens immediately rather than label and to delay operation until such processes have been implemented.

However, there are many uncertainties contained in this simple example. Because of the short time frame for labeling to begin, 60 days from publication of the final rule, many firms may not be able to purchase and install pasteurization equipment or find other means of validating a 5 log reduction in the target organism. It is unclear how manufacturers think that consumers will react to the warning signs, they may believe that their customers will not reduce their purchases of juice. Also, firms with larger sales or smaller pathogen reduction costs will need a smaller percentage sales decline from labeling in order to be induced to initiate 5 log pathogen controls early. Finally, it is unclear how many firms will have immediate access to the capital requirements imposed by this rule.

If, therefore, all processors which will eventually be covered by the HACCP rule do not label, then they have no direct labeling cost. The cost of the labeling rule to these processors is the extra expense that results from implementing HACCP 2 years earlier than would be required by the HACCP rule alone. This cost, as stated above, is $16,000 (discounted for 2 years at 7 percent). Of the 1,070 establishments covered by the HACCP rule, all of the 20 firms in the OEI which are also affected by the labeling rule (those estimated to be producing minimally processed juice) plus all of the 220 very small orange and apple juice processors covered by the HACCP rule are affected in this way (240 plants in all). The agency assumes, based on information from industry sources, that 30 percent of this set of processors (72 plants) have already initiated or are in the process of initiating pasteurization. Therefore, the total cost of the labeling rule for this set of processors is $2,688,000 ($16,000 x 168 plants).

The establishments that will need to display warning labeling are those 3,980 establishments covered by the labeling rule but not by the HACCP rule. Based on information learned from FDA's nutrition labeling rules, the average cost per placard (and periodic replacement) is estimated to be $100. This estimate will encompass the possibility that some firms may have to supply multiple signs to meet the requirement that it will be available at the point of purchase. Therefore, the total one-time cost for this set of processors is $398,000.

b. *Container labels (§ 101.17(f)(3)(ii)).* The cost of labeling is estimated by multiplying the number of affected separable labels on packaged products, normally referred to as stock keeping units (SKU's), by the cost of changing the label to add the warning. Table 24 shows FDA's estimate of the cost per SKU of placing a warning label on the information panel for different lengths of the compliance period. These costs decrease over time for several reasons. The primary reason is that manufacturers change labels or, at least, reorder them at regular intervals and a larger length of compliance period allows manufacturers to incorporate regulatory changes into planned changes.

TABLE 24.—LABEL CHANGE COSTS PER SKU FOR DIFFERENT LENGTHS OF THE COMPLIANCE PERIOD

	2 months	6 Months	1 Year	2 Years	3 Years
Administrative costs	$6,000	$1,800	$900	$450	$350
Redesign costs	$1,500	$450	$450	$50	$50
Inventory loss	$800	$250	$0	$0	$0

TABLE 24.—LABEL CHANGE COSTS PER SKU FOR DIFFERENT LENGTHS OF THE COMPLIANCE PERIOD—Continued

	2 months	6 Months	1 Year	2 Years	3 Years
Totals	$8,300	$2,500	$1,350	$500	$400

Processors of minimally processed packaged juice which are not covered by HACCP will need to add the warning to their package labels at the end of the 2-year compliance period. FDA estimates that 2,980 processors will be subject to this provision (1,440 very small apple juice retailers and 240 very small orange juice retailers exempted from the HACCP rule plus 1,300 grocery stores producing packaged juice). The total cost for this provision is $1,490,000 (2,980 x $500) at the end of the 2-year compliance period. For simplicity of reporting and calculation with the other labeling costs, this cost will be added as $1,301,000 (the present value of $1,490,000 discounted 2 years at 7 percent).

c. *Summary of likely labeling costs.* The agency estimates that the likely total cost of the labeling rule is a one-time cost of $4,387,000 ($2,688,000 + $398,000 + $1,301,000).

2. HACCP Costs

a. *CGMP's (§ 120.5).* This section of the proposal reaffirms the applicability of the CGMP's in part 110 in determining whether facility design, materials, personnel practices, and cleaning and sanitation procedures are safe.

No costs are attributed to this section for this rulemaking. The overwhelming majority of juice plants are in compliance with the CGMP's. In 1996 only 6 percent of the plants inspected were cited for official action. Therefore it is assumed that these rules will not have any effect on the enforcement of the CGMP's for juice products.

b. *Prerequisite program SOP's (§ 120.6).* FDA is proposing to require that processors control and document specific SOP's that provide a foundation for the HACCP system and to have and implement SOP's for prerequisite programs. In general, there are three activities that are part of prerequisite program SOP's: (1) Developing SOP's, (2) implementing sanitation controls with corrections of deviations from SOP's, and (3) monitoring and documenting for SOP's.

i. *Developing SOP's.* Each processor must have a sanitation SOP. FDA estimates that SOP's for juice plants could be developed with 20 hours of labor. At the rural hourly cost of labor ($13), the cost per plant of developing SOP's is approximately $260. If one half of the 900 domestic plants in the OEI and all of the 220 very small juice processors do not currently have SOP's, then they will have to develop them to comply with this regulation, if it is adopted. Under those assumptions, the total cost for the industry to develop SOP's would be approximately $174,200 ($260 x 670 plants).

ii. *Implementing sanitation controls with corrections of deviations from SOP's.* Each processor must implement a sanitation SOP and correct deviations from the prerequisite program SOP's in a timely fashion.

In 1996, 39 percent of the juice plants inspected were cited as VAI (voluntary action indicated). This citation usually indicates that an investigator noted deficiencies that were not significant enough to warrant an administrative or regulatory action but which should be corrected on a voluntary basis. Information from the inspection reports indicates that approximately 30 percent of the juice plants inspected had sanitation and food safety related deficiencies, 4 percent had deficiencies which were related to low-acid canned food regulations, and 4 percent had deficiencies for misbranding or mislabeling. Also in 1996, 6 percent of the juice plants inspected were cited as OAI (official action indicated). This citation indicates that an investigator noted deficiencies significant enough to recommend regulatory or administrative sanctions. Information from the inspection reports indicates that 3 percent of the juice plants had significant deficiencies that could be related to food safety or low-acid canned food regulations, 2 percent had significant deficiencies for misbranding or mislabeling.

On a few of the VAI inspection reports, FDA investigators indicated an estimate of the cost of correcting sanitation and food safety related deficiencies indicated. Two-thirds of the reports estimated costs of corrections at $0 to $99, and one-third of the reports estimated costs of corrections at $1,000 to $4,999.[8] Taking the middle of these ranges gives an average estimated cost of corrections of approximately $1,000 (($50 x 67 percent) + ($3,000 x 33 percent)) per plant for correcting sanitation and food safety related deficiencies.

The HACCP rule will mandate the implementation of daily monitoring of sanitation controls. This should make the correction of sanitation and food safety related deficiencies happen on the day that they occur rather than months later. Regulatory inspections of juice plants are made approximately once every 5 years. If food safety and sanitation related deficiencies occur on average approximately once every 5 years midway between inspections (to facilitate calculation), then the HACCP rule should cause corrections to be taken an average of 2.5 years earlier than would be the case without the rule. The cost of the rule, then, is not the full cost of taking the corrections. Those corrections would be taken even without the HACCP rule after the plant was inspected and the deficiencies noted. The cost of the HACCP rule is the present value of making the expenditures to correct the deficiencies at an earlier date than would take place otherwise. The present value of making an infinite series of $1,000 expenditures once every 5 years and 2.5 years earlier than they would otherwise occur is $500 when discounted at 7 percent.

Based on information from inspection reports, FDA assumes that about 30 percent of all 1,070 covered juice plants (about 320 plants) are not likely to have sanitation controls that are sufficiently implemented, but which do not warrant administrative or regulatory action. If it costs each of these 320 plants $500 to implement sanitation controls and to correct deviations from SOP's, then the total cost borne by the industry for this requirement is $160,000, which, because it is discounted, will be added as a one-time expenditure in the total costs.

iii. *Monitoring and documenting of SOP's.* All procedures in the prerequisite program SOP's are required to be conducted at the frequencies specified and implementation of these procedures will have to be monitored and documented.

FDA estimates that monitoring and documenting of SOP's will require one-half hour of labor per operating week. The cost per plant of SOP monitoring and documenting is given in Table 25.

[8] No reports estimated costs of $100 to $999.

TABLE 25.—ANNUAL PER PLANT COST OF SOP MONITORING AND DOCUMENTING

Production	Weeks of Operation per Year	Estimate Hrs. per Week for SOP Monitoring and Documenting	Wage ($/hour)	Estimate Annual SOP Monitoring and Documenting Cost per Plant
Seasonal	16	.5	$13	$100
Year round	52	.5	$13	$340

Table 26 shows the distribution of per plant and total industry costs based on the estimate in Table 25 for SOP monitoring and documenting needed to comply with this rule, if it is adopted. These estimates assume that no plants are currently in compliance with these particular requirements.

TABLE 26.—TOTAL ANNUAL COST OF SOP MONITORING AND DOCUMENTING

Production	Estimate Annual SOP Monitoring and Documenting Cost per Plant	No. of Plants	Estimate Annual SOP Monitoring and Documenting
Seasonal	$100	645	$64,500
Year round	$340	450	$153,000
Totals		1,095	$218,000

c. *Hazard Analysis and HACCP Plan (§§ 120.7 and 120.8).* Under the proposal, processors are required to have a written hazard analysis and to have and implement a written HACCP plan whenever a hazard analysis reveals a food hazard that is reasonably likely to occur. Requirements are set forth for the minimum contents of the plan and for the signing and dating of the HACCP plan by specified personnel. Failure of a processor to have and implement a HACCP system in compliance with this rule, if adopted, will render the food products of that processor adulterated.

i. *Hazard analysis and HACCP plan development.* Under the proposal, each plant is responsible for developing a written hazard analysis of hazards that are reasonably likely to occur in the product that a processor can control. The hazards to be considered are any chemical, physical, and biological hazards that may cause illness, injury, or death in humans. Plant management must determine the likelihood of occurrence of these hazards, either due to their introduction through material inputs or processing or a possible failure to eliminate them or to reduce them to acceptable levels in processing. Some Federal Government sampling and illness outbreak data are available to provide firms with a set of possible hazards that may affect a particular product and process. In addition, section V of this document, the accompanying appendix, and the preambles to these proposed rules contain information on most of the hazards that have caused problems in juice products in the past. Additional information may be forthcoming in the HACCP final rule (after FDA evaluates the comments). Experience from the HACCP pilot suggests that the hazard analysis for products similar to juice took 16 to 24 hours. FDA's preliminary estimate is that it will take approximately four individuals, including a plant manager; 5 hours each to complete the hazard analysis; and another 15 hours each to formulate the HACCP plan. The HACCP plan requires that the plant manager, quality control official and others establish critical control points (CCP's) for every hazard identified in the hazard analysis and critical limits at each CCP; establish a plan to monitor those CCP's; determine how deviations from critical limits will be handled; and establish procedures for verification and validation that the plan is being followed and that it is properly controlling the identified hazards. FDA assumes that part of this process will be to determine the most cost-effective means to comply with this regulation when developing the plan. Thus, the total number of person hours per plant to develop both documents is 80 hours. At $13 per hour the total cost per plant is about $1,000 per plant.

FDA has assumed that about 5 percent (50 plants) of all juice plants in the OEI will have implemented HACCP substantially in the form required by this regulation by the time that this regulation is finalized regardless of this regulatory action. This assumption is based on conversations with pilot plant firms who have indicated to FDA that many large firms have begun both to do HACCP and require HACCP of their suppliers. It is estimated that approximately 1,070 plants will need to do hazard analyses and develop HACCP plans to comply with this rule, if it is adopted. Therefore, the total cost of 1,070 plants at $1,000 each to develop a hazard analysis and a HACCP plan is approximately $1,070,000 million.

ii. *Pesticide HACCP controls.* Pesticides may be a component of material inputs that must be controlled. If a processor has direct knowledge of the amount of pesticide applied, either because the produce is from the processor's own farm or because records showing the application of pesticides accompanies the incoming produce, then the processor may control pesticide hazards by means of a supplier certificate. Under such an arrangement a supplier would only need to provide the processor with a certification that any pesticides had been properly applied to the produce so as not to exceed applicable tolerances. As each arrives at the processing plant, a worker will need to verify that the supplier for that shipment has supplied the processor with a proper and up-to-date certification. FDA assumes that verification of supplier certification requires 1 minute per shipment which, at $13 per hour, represents a cost per shipment of approximately $0.25.

FDA has estimated the number of shipments that will be verified in this manner by working backward from the amount of juice consumed. Annual juice consumption in the United States is 2.3 billion gallons (gal). The agency assumes that 80 percent of this total (1.84 billion gal) is produced by approximately 75 large firms (operating 225 plants). FDA believes that all large firms are currently doing a sufficient

amount of sampling and monitoring (or receiving supplier certificates) for pesticides. Therefore it is assumed that there are no costs for large firms to comply with this requirement. That leaves 20 percent of the total (460 million gal) produced by approximately 2,575 small and very small firms. FDA assumes that all small and very small firms use domestic produce only. If 15 pounds (lb) of produce are required to make 1 gal of juice, then small firms use 6.9 billion lb of domestic produce (460 million gal x 15 lb/gal). If 45,000 lb of produce (the amount carried by a typical tractor trailer) constitutes 1 shipment of produce, then small and very small firms use 153,000 shipments of produce (6.9 billion lb ÷ 45,000 lb/shipment).

However, for the purposes of this proposed regulation FDA is including as retailers very small businesses that make juice on their premises, whose total sales of juice and juice products do not exceed 40,000 gallons per year and who sell directly to consumers or directly to consumers and other retailers. This exemption decreases the percentage of juice processed under pesticide controls by approximately 14 percent thereby reducing the number of shipments of produce to 132,000 (153,000 x 86 percent).

FDA assumes that 80 percent of small and very small firms covered by the rule (676) will process shipments of produce that will be accompanied by supplier certifications of pesticide application after the HACCP rule is in place. Therefore, the number of shipments to be handled under prerequisite program controls is 106,000 (132,000 shipments x 80 percent) per year. Thus, this analysis assumes that the average small and very small plant receives approximately 160 (106,000 shipments ÷ 676 small plants) shipments per year. The total per plant cost is about $40 (60 shipments x $0.25/shipment) for the 676 small and very small plants that can control this issue in this way. Based on these calculations, the total marginal cost of this type of control for pesticides is approximately $27,000 ($40 x 676 plants).

If such records cannot be obtained, different types of controls need to be implemented. In this case, the processor must run pesticide residue tests to ensure that there are no pesticides either over tolerance or used on products for which there is no tolerance. To determine the frequency of such testing, processors may avail themselves of Government test results which indicate the likely variance of illegal residues over a particular crop or region.

Current records indicate that, for domestic crops, only about .25 percent (one-quarter of 1 percent) are out of compliance. Furthermore, as HACCP is adopted by more of the food industry, it is expected that records, for some types of produce, will routinely accompany produce intended for interstate commerce. However, many types of produce are currently commingled at different stages in the distribution network. This creates a problem for backtracking when there are either pesticide or pathogen problems.

There are two potential costs associated with ensuring that pesticide residues are legal: (1) Matching and shipping pesticide spray records with crops and (2) costs of multiresidue testing. If records are to accompany produce, fruits and vegetables may only be commingled if all of the commingled produce has records showing it is under tolerance. Otherwise, produce with paperwork must be kept separate from produce without such paperwork. In the latter case, if it is to be used to produce juice, multiresidue tests must be performed costing about $150 per test. Just as was calculated for supplier certificates, FDA calculates that there are 132,000 shipments which use 5,865 million pounds of produce that must be covered by pesticide controls. As 80 percent has been considered to be handled by supplier certificates, 20 percent of the remaining shipments must be covered by a sampling plan. Thus, of the 845 small plants total, 169 will cover an average of 160 shipments with a pesticide sampling plan. The number of shipments that must be tested is about 26,000 (132,000 x 20 percent) per year.

Because of the likelihood of a very low violation rate, approximately one-quarter of 1 percent, which is coupled with a maximum upper bound added risk of about 1 in a million lifetime cancer cases (see section V of this document), those processors who are unable to obtain supplier certificates should need to only sample lots periodically to ensure that such lots are in compliance. If the average number of shipments per plant per year is 160, processors could randomly sample 10 shipments per year and, assuming all were negative, could be assured with 80 percent confidence that there are no more than 14 percent violative lots in the entire season's produce input. Furthermore, if processors are turning up violative shipments, they are expected to take corrective action to prevent future shipments from being violative so that the rate of violative juice that reaches consumers is expected to stay extremely low. Thus, costs will be estimated for these processors based on 10 random samples per year at a cost of $150 per sample. Based on these calculations, the total marginal cost of pesticide testing is approximately $254,000 (10 tests x $150/test x 169 firms). Costs per plant are estimated to be an average of $1,500. Therefore, the total annual cost of pesticide control for the HACCP rule is $281,000 ($254,000 for pesticide testing + $27,000 for supplier certificate verification).

iii. *Pathogen HACCP controls.* Processors will need to include controls for microbial hazards in their HACCP plans and to implement these controls in their operations. Potential microbial hazards include both heat sensitive and heat resistant pathogens (and heat resistant toxins produced by pathogens), including viruses. However, FDA is interested in the safety of products as they are consumed, and any combination of controls that successfully controls pathogens will satisfy the requirements of this regulation. This regulation will allow each processor to choose the combination of control measures that cost-effectively controls microbial hazards. In addition, because of this ''performance'' nature of HACCP, manufacturers will be encouraged to continue to seek out and implement less costly and more effective methods.

Processors may attempt to control pathogens through other means, using a combination of several steps that are less effective separately, but which when used together will achieve adequate log reductions of pathogens. These methods may include control of contamination at the growing level, including use of potable water for irrigation, use of safe fertilizers, rejection of fruits dropped from trees onto the ground, and application of good sanitation practices during harvesting. Other controls that can be applied at the receiving, sorting, and processing levels include washing, brushing and sanitizing the product before extraction, acidifying the product, and using preservatives. FDA requests comments on potential costs and use of these or any other methods.

At present, pasteurization is the primary effective, commercially implemented method for controlling pathogens in juice. However, the agency is not proposing to require pasteurization in the proposed HACCP rule since other methods, either singularly or combined, may be as effective in achieving the 5-log reduction. However, the effectiveness and commercial feasibility of these other methods have not been established over a significant period of

time. It is possible that the effectiveness and feasibility of other methods will be established prior to the finalization of the HACCP rule, thus affording processors a less expensive means of pathogen control. To the extent that processors adopt other, less expensive pathogen controls, the costs for pasteurization estimated in this analysis will be an overestimate of the actual cost of the rule. The agency has estimated an option for carrying out pasteurization that it believes minimizes the cost of pasteurization. That is, the agency has estimated the costs of purchasing special, low cost pasteurizers designed for low-volume applications that are suited to small businesses. It is also worth mentioning that pasteurized juice products can be made using drops and culled produce, which significantly lowers the cost of the material inputs. Processes other than pasteurization may not be able to reduce pathogens sufficiently to accept this type of produce.

Another possibility, for which FDA has not estimated costs, is that processors that do not have pasteurizing equipment on site will ship their juice to a facility that can provide them with pasteurization and bottling service and then ship the bottled juice back for distribution. Juice and dairy plants are the facilities most likely to be able to provide this service. Purchasing the service of pasteurization may be a more cost-effective option for some juice processors.

In fact, some juice companies do contract out their juice making process. They blend the different varieties of raw produce for their product and then ship it to a processor. There the produce is washed and culled, pressed, pasteurized, bottled, and labeled. The juice is then picked up by the owner and distributed. Other juice companies have contracted out the pasteurization-bottling processes. They press the produce themselves, then ship the juice to a pasteurization-bottling facility to be pasteurized and bottled. Still other companies have contracted out the pasteurization process only. They press the produce themselves, then ship the juice to a pasteurization facility to be pasteurized, and then ship the pasteurized juice back in bulk for bottling and distribution. If some juice companies decide to take approaches similar to these in response to this rule, their operations will change fundamentally. Juice processors will choose the option which will result in the lowest marginal cost to produce juice. The agency has not included the estimate of the cost of contracting out pasteurizing because of: (1) The increased complexity of the HACCP plan to control for recontamination, (2) the problem of estimating processors' access to pasteurization equipment owned by other processors, and (3) the extra expense involved in transporting the products. All these cast serious doubt on the feasibility of this option for many very small processors. However, this analysis is uncertain and FDA would expect each manufacturer to examine the option of contracting their product to be pasteurized and taking advantage of this where it is less costly than purchasing their own equipment.

Another aspect of pathogen control which some processors may adopt, and for which FDA has not estimated costs, is juice refrigeration. Pasteurized juice which has not been heated to the degree so as to make it shelf stable must be refrigerated. This cost has not been investigated because the agency has assumed that producers of nonshelf stable juice are already refrigerating their products. The agency requests comment on this assumption and on the cost of refrigeration, if any, over and above that which is already being done.

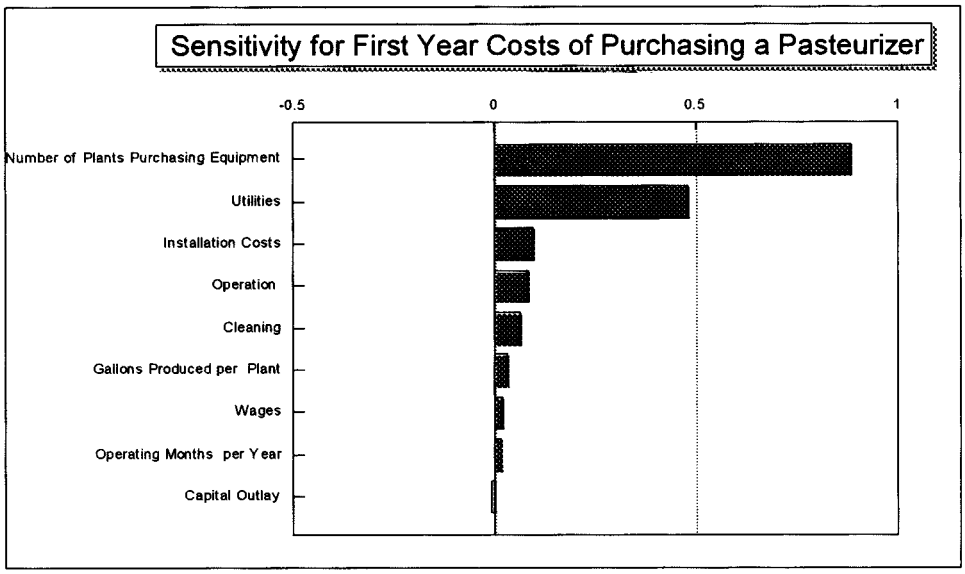
The costs of pasteurization vary depending on numerous factors, such as the capacity of the facility, and the amount of labor. In addition, there is uncertainty in the estimates of the number and size of the processors who will need to install pasteurization equipment, among other factors. Some makers of cider processing equipment are marketing pasteurization units for small processors. Medium sized pasteurization/heater/chiller units are reported to cost about $17,000 plus about $1,500 for installation. These units have the capacity necessary to meet the needs of a small processor producing about 400,000 gal of juice in a 4-month season.

Additionally, initial startup of pasteurization would require alterations in plant construction, design or layout to accommodate the additional processing step and equipment operator training. Also, there are operating expenses related to pasteurization including utilities, cleaning, maintenance and repair, and depreciation. Table 27 lists the parameter values that have been used in a Monte Carlo analysis to model the potential costs of installing and using pasteurization equipment by juice processors.

TABLE 27.—INPUTS AND RESULTS OF MONTE CARLO ANALYSIS OF INITIATING PASTEURIZATION

Parameter	10th Percentile	Mean	90th Percentile
Wage rates	$11.30	$13	$14.70
No. of operating months	2	6	9
Plant capacity (in gal)	34,000	74,000	124,000
Installation costs	$1,300	$1,500	$1,700
Cleaning hours (monthly)	52	60	68
Costs of the pasteurizer	$10,000	$17,000	25,000
Hours to operate (monthly)	26	30	34
Total Pasteurization Cost (per plant)	$18,200	$26,200	$34,800

The key variables that affect this analysis are shown in the ''tornado'' diagram, Figure 1.



For the purpose of this benefit-cost analysis, FDA has preliminarily concluded that it is unlikely that fresh orange (and possibly other citrus) juice processors will have to pasteurize their products to achieve a 5-log reduction when a HACCP program is adopted because of the nature of the fruits and the methods of juice extraction commonly used by industry. Therefore, costs for these processors are limited to the costs of creating and operating a HACCP system, not to purchasing pasteurizing equipment.

Of the 1,070 processors covered by the HACCP rule only a portion of these will need to initiate pasteurization. Table 28 shows FDA's assumption about the number of processors in the OEI of various types of juice that are not pasteurizing.

TABLE 28.—TYPES OF PLANTS CURRENTLY WITHOUT PASTEURIZATION

Type	No. Plants with Type as Primary Product	Best Estimate of Plants Minimally Processing
Berry	77	1
Citrus	211	10
Core	133	3
Mixed Fruit	36	1
Pit	31	1
Sub-tropical/tropical	29	1
Vine	2	0
Other	8	0
Beans/peas/corn	5	0
Fruits used as vegetables	41	1
Leaf/stem	8	0
Mixed vegetable	10	1
Root/tuber	8	1
Fruit beverage bases	37	0
Liquid fruit beverage bases	124	0
Combination true flavored and imitation flavored beverages	19	0
Liquid combination true flavored and imitation flavored beverages	55	0
Other beverage bases	28	0
Baby (infant and junior) fruits, juices and drinks	6	0
Totals	868	20

Of the 20 processors in the OEI assumed not to be pasteurizing, 10 of these are citrus juice processors and may not need to initiate additional controls beyond those already in place for controlling pathogens. That leaves 10 processors in the OEI assumed to need to initiate pasteurization. FDA's preliminary determination is that the 60 very small orange juice processors will not need to implement additional controls for pathogens than those already in place. Of the 160 very small apple juice processors the agency assumes, based on industry sources, that 30 percent (50) have already initiated or are in the process of initiating pasteurization because of both demand and supply effects.

The assumption that 30 percent of apple juice processors have already initiated pasteurization follows from the adverse publicity concerning unpasteurized juice. On the demand side, both consumers and retailers have become more aware of the hazards associated with unpasteurized juice over the last 5 years. From 1992 to 1997, in two national newspapers, the number of articles concerning the safety of apple juice doubled. On the supply side, producers have certainly become aware of the problems associated with their

unpasteurized juice both due to the efforts of FDA and from the news media. For example, in the five states with the largest number of apple juice processors (New York, Ohio, Michigan, Illinois, and Pennsylvania), articles in major newspapers about the safety of juice increased 13 percent between 1992 and 1997. This awareness constitutes action on the supply side as producers contemplate the potential liability and loss in sales (from a loss of goodwill) associated with producing a potentially unsafe product. That leaves 110 very small apple juice processors to implement pasteurization in order to control pathogens as required in the HACCP rule. Table 29 shows the first year total cost of pathogen control attributable to the HACCP rule.

TABLE 29.—FIRST YEAR COST OF PATHOGEN CONTROL ATTRIBUTABLE TO HACCP PROPOSAL

Processor Type	Cost per Plant	No. of Plants	Total
Very small apple juice processors	$18,200	110	$2,002,000
Juice processors in the OEI	$34,800	10	$348,000
Total			$2,350,000

Pasteurization will require ongoing costs for operation and maintenance. FDA estimates these annual costs for labor, utilities, and materials subsequent to the first year to be $7,000 per year for very small processors and $8,000 per year for processors in the OEI. These estimates can be derived from Table 27 by subtracting the cost of the pasteurizer and installation from the total pasteurization cost for the 10th and 90th percentile estimates. The total cost of pathogen control in subsequent years is given in Table 30.

TABLE 30.—SUBSEQUENT YEAR COST OF PATHOGEN CONTROL ATTRIBUTABLE TO HACCP RULE

Processor Type	Cost per Plant	No. of Plants	Total
Very small apple juice processors	$7,000	110	$770,000
Juice processors in the OEI	$8,000	10	$80,000
Total			$850,000

There are other costs that are related to processing for pathogen control. The pasteurization of juice causes changes in the characteristics of the products, primarily in terms of texture and taste. Some current consumers of nonheat-treated juice will bear the costs of losing a particular product as well as costs of searching for products with the characteristics that they prefer the most. Thus, one cost of these regulations is the loss of ''fresh'' juice, that is, juice that is not heat (or otherwise) processed. The appropriate measure of the loss of a product is the sum of producer and consumer surplus. Consumer surplus is a measure of the value that consumers obtain from a product. It is measured by what consumers would be willing to pay for a product over and above what they actually must pay. Producer surplus is a measure of the amount of rent producers receive, the price minus the cost of production. Measurement of consumer surplus depends on several factors that influence the shape of the demand curve; the most important one in this case being the substitutability of other juice products. If a product has close substitutes in the minds of consumers, the amount of both producer and consumers surplus is smaller. In addition, if there are attributes that consumers do not perceive or are not informed about, such as additional nutritional benefits associated with the lost product, there may be additional costs of losing that product. FDA has no information on how readily consumers will accept pasteurized juice in the place of fresh juice nor any other information that could be used to estimate that cost.

iv. *Glass and direct food additive HACCP controls.* FDA has not attributed any costs for control of glass or direct food additives even though these potential hazards are among those that are likely to be relevant for juice. There have been some recalls in recent years for each of these two hazards. However, glass is a food safety hazard that is readily recognized by consumers who can hold producers accountable for its presence in food. Thus, the agency believes that processors packing juice in glass are already currently implementing every feasible control for this potential hazard in order to limit their liability and to provide consumer protection. Additionally, although approximately 25 percent of the processing plants pack juice in glass containers, this number is diminishing rapidly for economic and safety reasons.

Regarding food additives, many juice products contain food or color additives for the purpose of coloring or extending product shelf life. However, the agency believes that processors using direct food additives in juice are already currently implementing sufficient controls for these potential hazards as they are strictly regulated by FDA.

Even though processors may need to institute some additional monitoring and recordkeeping for these hazards after implementing HACCP, the agency believes that the additional cost will be negligible. Therefore, there is zero marginal cost associated with control for direct food additives, and there is zero marginal cost (and zero marginal benefits) associated with HACCP controls for glass.

v. *Natural toxin controls.* Processors of juice using imported apple juice will need to implement controls for the natural toxin, patulin. Patulin is a natural toxin that is found in apple juice made from moldy apples and is a hazard that is more likely to occur in imported apple juice products. Processors of juice using imported apple juice will need to implement controls by testing for this toxin.

FDA has estimated the number of shipments that will be tested for patulin by working backward from the amount of apple juice imported. About 200 million gallons of apple juice are imported into the United States by 7 large firms (operating 23 plants) annually. FDA assumes that all small firms use domestic produce only. Therefore, there are no costs accruing to small firms from this requirement.

If 15 lb of produce are required to make 1 gallon of juice, then large firms use 3 billion lb of foreign apples imported in the form of apple juice (200

million gal x 15 lb/gal). If 45,000 lb of apples (the amount carried by a typical tractor trailer) constitute 1 shipment of apples, then large firms use 66,667 shipments of imported apples (3 billion lb ÷ 45,000 lb/shipment). Thus, this analysis assumes that the average number of imported apple shipments per year to each large plant (which are the likely importers) is approximately 2,900 (66,667 shipments ÷ 23 plants).

The agency does not know the current frequency of shipments of apples containing patulin at violative levels. However, the agency assumes that the 23 large plants will randomly sample 30 shipments per year at a cost of $150 per sample. The total marginal cost of patulin testing is approximately $104,000 (30 tests x $150/test x 23 firms). Costs per plant are $4,500. If any lots are found positive, costs will be incurred that are estimated in section VI.B.1.d.i of this document.

d. *Corrective actions (§ 120.10).*—i. *Corrective action plan.* Most processors will have a corrective action plan that specifies the appropriate action to be taken for the violation of each critical limit. If a processor does not have a corrective action plan then the processor must revalidate the HACCP plan whenever a deviation occurs.

The development of a corrective action plan for juice products is less expensive than revalidation after each deviation from a critical limit. FDA estimates that a corrective action plan for juice products can be developed in 4 hours with a cost per plant of approximately $50 (about 4 hours of management time).

Approximately 1,070 plants will develop corrective action plans to comply with this rule, if adopted. Therefore, the total cost of 1,070 plants at $50 each to develop corrective action plans is approximately $54,000.

ii. *Corrective actions.* The implementation of HACCP requires that corrective actions be taken when critical limits are violated although deviations should be infrequent. The agency is expecting that those juice plants that pasteurize will establish a minimum of two CCP's: One for pathogens and one for pesticides. Firms may already have established CCP's for metal or glass for which no marginal costs or benefits are counted in this analysis. In addition, processors using imported apple juice may need to establish a CCP for patulin. Citrus juice producers may establish three CCP's, culling, washing and brushing, and pesticides. This analysis has assumed that pathogens will be controlled by pasteurization for noncitrus juices. Pasteurizers are designed to sense the temperature at which the product comes out of the pasteurizer and automatically recirculate the product if it has not been heated sufficiently. Therefore, corrective actions for pasteurization should be so rare as to be negligible for this analysis. FDA believe that virtually all citrus processors are currently monitoring the culling, and washing and brushing steps. Based on data from FDA pesticide sampling, violations of critical limits for pesticide should also be rare.

Some plants may choose to have multiple critical limits for pesticides because of the nature of the hazard they present (i.e., chronic). The stringency of the corrective action could vary directly with the critical limits. For example, if the first (lowest) critical limit were exceeded, the corrective action could be to investigate the problem. A violation of a higher limit, possibly one that could present an acute problem, would cause the product to be destroyed. As an upper-bound estimate, this analysis will assume that: (1) Deviations of pesticide and natural toxin critical limits occur once per month in each plant in the first year and once per quarter in subsequent years, (2) each corrective action requires 1 hour of labor to resolve, and (3) the cost of reconditioning is $100 per corrective action. The cost per plant is highly dependent upon the number of months that the plant is in operation.

Assuming that seasonal plants operate 4 months per year and all other plants operate 12 months per year, Tables 31 and 32 show the estimated first year and subsequent year costs of corrective actions per plant as well as the distribution of costs and total industry cost for the corrective actions needed to comply with this rule, if adopted.

TABLE 31.—COST OF FIRST YEAR CORRECTIVE ACTIONS

Production	Months of Operation per Year	No. of Deviations per Month	No. of Labor Hours per Deviation	Wage ($/h)	Cost of Reconditioning per Deviation	Cost per Plant First Year	No. of Plants	Totals
Seasonal	4	1	1	$13	$100	$150	645	$97,000
Year Round	12	1	1	$13	$100	$260	425	$111,000
Totals							1,070	$208,000

TABLE 32.—COST OF SUBSEQUENT YEAR CORRECTIVE ACTIONS

Production	Months of Operation per Year	No. of Deviations per Year	No. of Labor Hours per Deviation	Wage ($/h)	Cost of Reconditioning per Deviation	Cost per Plant Subsequent Year	No. of Plants	Totals
Seasonal	4	.25	1	$13	$100	$40	645	$26,000
Year Round	12	.25	1	$13	$100	$70	425	$30,000
Totals							1,070	$56,000

e. *Validation and verification (§ 120.11).*—i. *Verification.* HACCP coordinators need to verify at least weekly by record review that the HACCP plan is being followed, and calibrate process-monitoring instruments weekly.

If record review for verification requires 1 hour per operating week and the calibration of instruments used for monitoring critical limits requires 1 hour per week, then the verification cost per plant per production cycle is given in Table 33.

TABLE 33.—COST OF VERIFICATION

Production	Weeks of Operation per Year	H per Week for Verification	Wage ($/h)	Verification Cost per Plant	No. of Plants	Totals
Seasonal	16	2	$13	$420	645	$271,000
Year round	52	2	$13	$1,350	425	$574,000
Totals					1,070	$845,000

ii. *Validation.* Processors will need to validate their HACCP plans during the first year after implementation and at least annually, or whenever any changes occur that could affect or alter the hazard analysis, or HACCP plan. Further, if the processor does not have a HACCP plan because there are no hazards that are reasonably likely to occur, the processor must reassess their hazard analysis when any significant changes occur. Examples of things that may change include: (1) Raw material specifications or sources of raw materials, (2) product formulation, (3) processing methods or systems, (4) packaging, (5) finished product distribution systems, or (6) intended consumers or use by consumers. The purpose of validation is to determine that the HACCP plan is adequate to control food-safety hazards.

Validation is intended to answer several specific questions. These include: (1) Have all hazards been identified, (2) have the most appropriate control measures been identified, (3) are the critical limits appropriate, (4) does the monitoring measure what is needed to determine that the critical limits are being met, (5) are the right records being collected to tell whether the system is working properly, (6) are the right corrective measures being taken to ensure that any defective product is controlled properly, and (7) are the verification procedures adequate to provide assurance that the plan is being followed? If the processor addresses each of these several questions and the response to each is positive, then the processor can say that his plan has been validated and is working.

Each processor's operation will be unique and will require a validation approach adapted to the specific operation. Each approach may need to involve multiple activities since there is no one measurement or indicator to use to validate the hazard analysis and the HACCP plan. There are several factors that have been considered to determine the potential costs associated with these activities.

Validation may only be performed by an individual who has received training in an FDA-approved course. However, no additional costs are assigned to this requirement because the same training that is needed to perform the hazard analysis and prepare the HACCP plan will meet this need and is estimated in section VI.B.2.f.g.i of this document.

No one type of validation will work for all processors of fruit and vegetable juices for all types of hazards. For example, validation that a pasteurizer is attaining the desired ''kill'' level for a particular type of product and volume will be considerably different from validating that illegal pesticide residues are not present in the product. Three potential types of validation activities are: (1) Reviewing HACCP documents and scientific literature, (2) challenge studies, and (3) product testing.

The trained individual may periodically review all plant HACCP documents, including the HACCP plan and the hazard analysis, to determine if they are consistent with scientific literature. It is expected that industry trade publications will serve as a ready source of this information. Challenge studies, such as for pasteurizing units, determine the limits of the processing equipment and the unique parameters that need to be set to achieve the desired results. However, in some cases, simply relying on manufacturers specifications will be sufficient. Finally, it is expected that at least some end-product testing will take place. If, for example, processors are unsure of residue levels because of pooled raw inputs, they will need to test some finished product. In addition, some processors may find it useful to perform periodic microbial testing of wash water or incoming raw product. However, because of the sporadic nature of many of the hazards that must be considered in these products, testing alone may not be sufficient validation.

FDA estimates that validation is likely to take place twice per year for the 425 plants that operate year round and once per year for the 645 plants that operate seasonally. Validation of the SOP's and HACCP plan is likely to require hiring a food science and technology consultant (presumably, the same person hired to perform other HACCP-related services) for the approximately 845 plants that are small businesses. The costs estimated are assumed to cover both human and capital costs to accomplish the mix of likely validation activities (literature review, challenge testing, and product or water testing). FDA estimates that such consultant services cost approximately $1,000 per validation in the first year (assuming that consultant's services cost $1,000 per day and that the validation process takes a single day of the consultant's time). The agency estimates that in subsequent years a consultant will be able to validate the system in one-half of a day. There are approximately 75 large firms operating 225 plants who are likely to have the resources available to perform the validation functions inhouse. For large firms, FDA estimates that validating SOP's and HACCP plans will require 25 percent of the level of effort taken for the original SOP and HACCP plan development ($600). Because FDA has assumed that about 5 percent (50 plants) of all juice plants in the OEI would have voluntarily implemented HACCP substantially in the form required by this regulation by the time this regulation is finalized, only 175 large plants are affected. Tables 35 and 36 give the estimated cost for validation in the first and subsequent years.

TABLE 34.—COST OF FIRST YEAR VALIDATION

Plant Type	Cost of SOP Development	Cost of HACCP Plan Development	Ratio of Validation to Development Level of Effort	Validation Cost per Plant	No. of Validations per Year	No. of Plants Affected	Total
Seasonal small businesses				$1,000	1	645	$645,000
Year round small businesses				$1,000	2	250	$500,000
Year round large businesses	$260	$2,100	.25	$600	2	175	$210,000
Total							$1,355,000

TABLE 35.—COST OF SUBSEQUENT YEAR VALIDATION

Plant Type	Cost of SOP Development	Cost of HACCP Plan Development	Ratio of Validation to Development Level of Effort	Validation Cost per Plant	No. of Validations per Year	No. of Plants Affected	Total
Seasonal small businesses				$500	1	645	$323,000
Year round small businesses				$500	2	250	$250,000
Year round large businesses	$260	$2,100	.13	$300	2	175	$105,000
Total							$678,000

f. *HACCP records (§ 120.12).*—i. *Monitoring and recordkeeping.* Processors will need to monitor CCP's and keep HACCP system records of observations at the CCP's. Even for those plants that have necessary controls in place, plants without HACCP are not likely to be doing the amount of monitoring and recordkeeping that HACCP requires. Therefore, all processors that have not already implemented HACCP will need to increase monitoring and recordkeeping activities.

If the additional monitoring and recordkeeping that needs to be done throughout the entire plant is equivalent to 5 percent of one worker's time (3 minutes per hour of operation per plant), then the cost is dependent on the number of days that the plant is in operation and the number of hours that it operates per day.

Assuming seasonal plants operate 12 hours per day for 120 days per year and year round plants operate 24 hours per day for 360 days per year, then Table 36 shows the annual cost of additional monitoring and recordkeeping per plant. It also shows the distribution of per plant costs and total industry costs for the additional monitoring and recordkeeping needed to comply with this proposed rule.

TABLE 36.—COST OF MONITORING AND RECORD KEEPING

Production	Hours of Operation per Day	Days of Operation per Year	Wage ($/h)	Percent Additional Time	Cost per Plant per Year	No. of Plants	Totals
Seasonal	12	120	$13	5%	$900	645	$581,000
Year round	24	360	$13	5%	$5,600	425	$2,380,000
Totals						1,070	$2,961,000

ii. *Record maintenance.* The records produced for this regulation will need to be maintained for use by both the processor and regulators.

Assuming record maintenance requires 1 h per week while the plant is being operated then the annual cost of record maintenance per plant is described in Table 37.

TABLE 37.—COST OF RECORD MAINTENANCE

Production	Weeks of Operation per Year	Hours per Week Maintaining Records	Wage ($/h)	Cost per Plant	No. of Plants	Totals
Seasonal	16	1	$13	$210	645	$135,000
Year round	52	1	$13	$680	425	$289,000
Totals					1,070	$424,000

iii. *Record storage.* Records produced for this regulation will need to be stored for use by both the processor and regulators. A single standard office file drawer should be sufficient to store the proposed records for the proposed duration. If for storage of the additional records each plant needs to purchase one standard office file cabinet at approximately $150 each, then the total cost of record storage for the 1,070 plants is approximately $161,000.

g. *Training (§ 120.13).*—i. *HACCP coordinator training.* Processors may need to employ a HACCP coordinator to carry out the duties specified for such a person. In order to train one employee at a 3-day course that has a curriculum consistent with FDA's standards, a processor will need to pay course tuition, travel and lodging (assuming that there is not a course in the immediate area), and replacement of the labor that the employee would have provided at the processing plant if the employee had not attended the course. Table 38 shows the estimated costs for each of these items and the estimated total cost per plant for training a HACCP coordinator.

TABLE 38.–COST OF HACCP COORDINATOR TRAINING

Tuition	Travel and Lodging	Foregone Labor Hours	Wage ($/h)	Total Cost per Plant
$500	$500	24	$13	$1,300

FDA estimates that if each of the 1,070 processing plants that are not currently estimated to have HACCP have a single employee trained by a course that is acceptable to the agency, then the total industry cost is $1,391,000 million.

ii. *Employee training in HACCP.* Each processor will need to train employees in their HACCP-related activities and may need to provide training for some employees to enable them to read and write English.

Each processor will need to train some of their employees as to how to perform their HACCP-related activities. From the OEI and the American Business Listing data, FDA has information on the distribution of employment for juice plants in the OEI. FDA has assumed that all of the 220 very small orange and apple juice processors employ three people on average. FDA has also assumed that the 50 plants that have implemented HACCP are the 50 plants with the largest number of employees. This analysis assumes that each plant must train 5 employees or 10 percent of their employees in HACCP-related responsibilities, whichever is greater. Table 39 describes the cost of training each employee for 8 hours annually, total employment in the affected plants and the total cost of this level of training.

TABLE 39.—COST OF EMPLOYEE TRAINING

No. of Annual Hours of Training per Employee	Wage ($/h)	Annual Cost per Employee	Average Plant Employment	No. of Employees Trained per Plant	No. of Plants	No. Plants With HACCP Implemented	Total No. of Employees Trained	Total
8	$13	$100	3	3	252	0	756	75,600
8	$13	$100	7	5	35	0	175	17,500
8	$13	$100	15	5	68	0	340	34,000
8	$13	$100	35	5	100	0	500	50,000
8	$13	$100	75	8	103	0	824	82,400
8	$13	$100	175	18	161	0	2,898	289,800
8	$13	$100	375	38	59	0	2,242	224,200
8	$13	$100	750	75	25	16	675	67,500
8	$13	$100	3,000	300	14	14	0	$0
8	$13	$100					8,910	$841,000

h. *Imports and foreign processors (§ 120.14).*—i. *Importers.* Information from the U.S. Customs Service indicates that approximately 120 importers import juice into the United States. The import provisions of the HACCP proposal will, in practice, cause importers to implement written procedures to ensure that the juice is produced under HACCP or equivalent safeguards. The importer may keep file copies of the foreign processor's HACCP plan, written guarantees that the product was produced in accordance with the HACCP plan, or certificates of inspection from foreign Governments. The importer may also have to inspect the foreign plant or test the imported product. Written records of all HACCP actions must be maintained by the importer. Some combination of records from the foreign processor and safeguards provided by the importer will become necessary to meet the requirements of this proposed rule. The agency estimates that the cost of these activities will be $10,000 per importer in early years, decreasing as memorandum of understandings with exporting countries are established.

ii. *Foreign juice processors.* The agency does not have any direct information on the number of foreign juice plants that export to the United States. However, approximately 75 percent of U.S. juice consumption is supplied by 900 plants in the OEI. Approximately 25 percent of U.S. juice consumption is supplied by foreign firms. This analysis assumes that the ratio of the number of domestic plants in the OEI to domestic production is equivalent to the ratio of the number of foreign exporters to foreign juice imports. The result of this assumption is an estimate of 300 foreign plants exporting to the United States that will need HACCP. FDA requests information from foreign governments and importers on the number of exporting juice plants in their respective countries.

Using this estimate for the number of juice exporting plants, if the cost per plant for initiating HACCP is same as for a large U.S. plant which is already pasteurizing juice (since all juice exported to the United States is pasteurized), then the first year cost per foreign juice exporter is approximately $26,000, and the cost in subsequent years is $22,000. Therefore the total cost in the first year for 300 foreign processors is approximately $8 million and approximately $7 million in subsequent years.

Table 45 in the Initial Regulatory Flexibility Analysis, which follows, shows typical costs for a large plant which has not already implemented HACCP. The agency assumes that these costs are representative of foreign plants exporting to the United States. The largest point of uncertainty in this estimation relates to the cost of employee training. The average domestic juice plant which employs 500 or more people has approximately 830 employees. This analysis assumes that 10 percent of these employees will need to be trained in HACCP-related duties. If training costs $100 per employee then the cost of employee training alone in a large plant is $8,300. Some plants employ more than 3,000 employees. For such a plant the cost of employee training would be $30,000. The agency request comment on the cost to foreign processors.

Table 40 lists types of juice exported to the United States and the various countries producing the juice. This is not a complete list of countries exporting juice to the United States, nor is it a comprehensive list of juice products.

TABLE 40.—SOURCES OF IMPORTED JUICE

Apple Juice	Grape Juice	Citrus Juice	Prune Juice	Pineapple Juice	Vegetable Juice
Argentina	Argentina	Argentina			
Australia		Australia			
Austria	Austria	Austria			
Belgium-Luxembourg	Belgium-Luxembourg	Belgium-Luxembourg	Belgium-Luxembourg		
		Belize			
	Brazil	Brazil		Brazil	
Canada	Canada	Canada	Canada		Canada
Chile	Chile				
Denmark					
		Dominican Republic			
France	France	France	France		
		Honduras		Honduras	
Hungary					
Israel	Israel	Israel			Israel
Italy	Italy	Italy			
		Jamaica			
		Japan			Japan
		Leeward/Windward Islands			
Mexico		Mexico		Mexico	
Netherlands					
New Zealand					
				Philippines	
Germany	Germany	Germany	Germany		
		South Korea			
				Singapore	
Spain					
Switzerland					Switzerland
				Taiwan	Taiwan
				Thailand	
Turkey					
Yugoslavia					

Table 40 is provided to give information about the scope of countries and products covered by these rules. The agency believes that a high estimate of the number of firms exporting juice to the United States is 300. Because the quality of the juice must be maintained during transport, all juice exported to the United States is currently processed in such a way so as to appropriately address potential pathogens. However, the agency has no information to suggest that any foreign juice processors have implemented HACCP in their operations.

C. Summary of Costs for Labeling and HACCP Rules

The total quantified costs are approximately $26 million in the first year and $15 million in all subsequent years. There will be a substantial impact on those processors who are producing minimally processed juice in that some will stop making the product, some will implement HACCP, and some will label. Table 41 summarizes costs of the rules by provision.

TABLE 41.—TOTAL FIRST YEAR AND RECURRING COST PER ACTIVITY

Activity	First Year Costs	Recurring Costs
Labeling Costs	$4,387,000	
Develop SOP's	$174,000	
Sanitation SOP's	$160,000	
Monitoring and documenting for SOP's	$218,000	$218,000
Hazard analysis and HACCP plan	$1,070,000	
Pesticide controls	$281,000	$281,000
Pathogen controls	$2,350,000	$850,000
Natural toxin controls	$104,000	104,000
Corrective action plan	$54,000	
Corrective actions	$208,000	$56,000
Verification	$845,000	$845,000
Validation	$1,355,000	$678,000
HACCP monitoring and recordkeeping	$2,961,000	$2,961,000
Record maintenance	$424,000	$424,000
Record storage	$161,000	
HACCP coordinator training	$1,391,000	
Employee training	$841,000	$841,000
Importers	1,200,000	600,000
Foreign processors	8,000,000	7,000,000
Totals	$26,184,000	$14,858,000

VII. Summary of Benefits and Costs

FDA has examined the costs and benefits of the proposed rules as required under Executive Order 12866. FDA finds that the costs and benefits of these rules have different values in subsequent years such that, to compare them properly, they must be discounted to the present year (the point at which a decision must be made). The quantified benefits (discounted annually at 7 percent) are expected to range from $3 billion to $ 4 billion and the quantified costs (discounted annually at 7 percent) are expected to be $240 million.

VIII. Initial Regulatory Flexibility Analysis

FDA has examined the impact of the two proposed rules as required by the RFA (5 U.S.C. 601–612). If a rule has a significant impact on a substantial number of small entities, the RFA requires agencies to analyze options that would minimize the economic impact of that rule on small entities. The agency acknowledges that these proposed rules are likely to have a significant impact on a substantial number of small entities.

A. Objectives

The RFA requires a succinct statement of the purpose and objectives of any rule that will have a significant impact on a substantial number of small entities.

The warning label proposal responds to the need to alert consumers to the potential risk of foodborne illness from consumption of juice products not pasteurized or otherwise processed to destroy pathogens that may be present. FDA is proposing to require warning labels on such juice products to inform consumers of the potential hazard of pathogens in such products; such labeling will not be required for juice that is processed to achieve a 5-log reduction. Once HACCP is implemented, the warning labeling will no longer be required for those products covered by the HACCP rule. The HACCP rule is being proposed to ensure that juice manufacturers control all physical, chemical, and microbial hazards in their products.

B. Definition of Small Business and Number of Small Businesses Affected

The RFA requires a statement of the definition of small business used in the analysis and a description of the number of small entities affected.

Table 42 shows the definition of small business for each type of establishment affected and a description of the number of small entities affected by each of the rules. The agency has accepted the Small Business Administration (SBA) definitions of small business for this analysis.

TABLE 42.—APPROXIMATE NUMBER OF SMALL PLANTS COVERED BY THESE RULES

Type of Establishment	Standard Industry Classification Codes	SBA Definition of Small by Category	Percentage of Category Defined as Small by SBA	No. of Small Establishments Covered by HACCP Rule	No. of Small Establishments Covered by Labeling Rule
Juice manufacturers in the OEI	2033, 2037	Less than 500 employees	75%	675	20

TABLE 42.—APPROXIMATE NUMBER OF SMALL PLANTS COVERED BY THESE RULES—Continued

Type of Establishment	Standard Industry Classification Codes	SBA Definition of Small by Category	Percentage of Category Defined as Small by SBA	No. of Small Establishments Covered by HACCP Rule	No. of Small Establishments Covered by Labeling Rule
Roadside-type apple juice makers	2033, 2037	Less than 500 employees	100%	160	1,600
Roadside-type orange juice makers	2033, 2037	Less than 500 employees	100%	60	300
Grocery stores and supermarkets processing at the point of sale	5411	Less than $20,000,000 per yr.	85%		1,100
Grocery stores and supermarkets	5411	Less than $20,000,000 per yr.	85%		1,450
Totals				895	4,470

C. Description of the Impact on Small Entities

1. Costs to Small Entities

Because there is a broad distribution of products covered, firm types, current processing practices and sizes, it would be misleading to report average per firm costs. However, some idea of the costs can be gained from the following examples. The impacts that the costs will have on a firm will vary depending on the total revenue derived from juice by a firm and the profit (return on sales) associated with juice production. Data on food manufacturing firms indicates that 75 percent of firms have return on sales of less than 5 percent.

The first example (Table 43) is of a small apple cider plant that is now producing nonheat-treated juice, buying commingled fruit, and has not developed or implemented sanitation SOP's. This plant will need to buy a pasteurizer (or find and validate a different process that achieves a 5-log reduction) and do some pesticide testing. The next example (Table 44) is a small plant that is producing pasteurized orange juice year round with fruit from a known source, and that has already developed and implemented sanitation SOP's (except that records have not been kept on SOP's). These two plants can be compared to a very large apple juice plant (Table 45) that imports some apples and therefore must test for patulin, and has not developed or implemented sanitation SOP's.

TABLE 43.—COSTS FOR ILLUSTRATIVE SMALL APPLE CIDER PROCESSOR

Type of Cost	Cost in First Year	Cost in Subsequent Years
Develop SOP's	$260	
Sanitation SOP's	$500	
Monitoring and documenting of SOP's	$100	$100
Hazard analysis and HACCP plan	$1,000	
Pesticide testing controls	$1,500	$1,500
Pathogen controls	$18,200	$7,900
Corrective action plan	$50	
Corrective actions	$150	$40
Verification	$420	$420
Validation	$1,000	$500
HACCP monitoring and recordkeeping	$900	$900
Record maintenance	$210	$210
Record storage	$150	
Training of coordinator	$1,300	
Employee training	$300	$300
Totals	$26,000	$11,900

TABLE 44.—COST FOR ILLUSTRATIVE SMALL ORANGE JUICE PROCESSOR

Type of Cost	Cost in First Year	Cost in Subsequent Years
Monitoring and documenting of SOP's year round	$340	$340
Hazard analysis and HACCP plan	$1,000	
Pesticide controls	$60	$60
Corrective action plan	$50	
Corrective actions	$260	$70
Verification	$1,350	$1,350
Validation	$2,000	$1,000
HACCP monitoring and recordkeeping	$5,600	$5,600
Record maintenance	$680	$680
Record storage	$150	
Training of coordinator	$1,300	
Employee training	$300	$300

TABLE 44.—COST FOR ILLUSTRATIVE SMALL ORANGE JUICE PROCESSOR—Continued

Type of Cost	Cost in First Year	Cost in Subsequent Years
Totals	$13,100	$9,400

TABLE 45.—COSTS FOR ILLUSTRATIVE VERY LARGE APPLE JUICE PROCESSOR

Type of Cost	Cost in First Year	Cost in Subsequent Years
Develop SOP's	$260	
Sanitation SOP's	$500	
Monitoring and documenting of SOP's	$340	$340
Hazard analysis and HACCP plan	$1,000	
Natural toxin control	$4,500	$4,500
Corrective action plan	$50	
Corrective actions	$260	$70
Verification	$1,350	$1,350
Validation	$1,200	$1,200
HACCP monitoring and recordkeeping	$5,600	$5,600
Record maintenance	$680	$680
Record storage	$150	
Training of coordinator	$1,300	
Employee training	$8,300	$8,300
Totals	$26,000	$22,000

2. Professional Skills Required for Compliance

The RFA requires a description of the professional skills required for compliance with this rule. Table 46 describes the professional skills required for compliance with the various activities required by this rule.

TABLE 46.—PROFESSIONAL SKILLS REQUIRED FOR COMPLIANCE

Required Activity	Section of Proposal	Professional Skills Required for Compliance
Developing prerequisite program SOP's	§ 120.6	Managers familiar with incoming materials and plant sanitation
Implementing sanitation controls with corrections of deviations from prerequisite program SOP's	§ 120.6	Production workers who are able to maintain the sanitation controls as described in the sanitation SOP's and supervisors or managers who can determine what corrective actions are necessary for deviations from SOP's
Monitoring and documenting of prerequisite program SOP's	§ 120.6	Production workers who are appropriately trained to monitor and keep records on observations and measurements for prerequisite program SOP's
Developing hazard analysis and HACCP plan	§§ 120.7 and 120.8	Supervisors or managers who fulfill the role of HACCP coordinator as well as microbiologists, chemists, and attorneys
Implementing pesticide controls	§§ 120.7 and 120.8	Production workers who are appropriately trained to carry out tests, to monitor, and to keep records on observations and measurements at critical control points
Implementing pathogen controls	§§ 120.7 and 120.8	Production workers who are appropriately trained to monitor and keep records on observations and measurements at critical control points
Taking corrective actions	§ 120.10	Production workers who are trained to take corrective actions described in corrective action plans and supervisors or managers who can determine what corrective actions are necessary for deviations from critical limits
Verification	§ 120.11	Supervisors or managers who fulfill the role of HACCP coordinator
Validation	§ 120.11	Food scientists or food technologists who can perform a scientific review of the process
Monitoring and recordkeeping	§ 120.12	Production workers who are appropriately trained to monitor and keep records on observations and measurements at critical control points
Record maintenance	§ 120.12	Clerical or production workers
HACCP coordinator training	§ 120.13	Supervisors or managers who fulfill the role of HACCP coordinator
HACCP employee training	§ 120.13	Clerical and production workers

TABLE 46.—PROFESSIONAL SKILLS REQUIRED FOR COMPLIANCE—Continued

Required Activity	Section of Proposal	Professional Skills Required for Compliance
Imports	§ 120.14	Clerical workers as well as supervisors or managers who fulfill the role of HACCP coordinator

3. Recordkeeping requirements

The RFA requires a description of the recordkeeping requirements of the proposed rule. Table 47 shows the provisions for which records need to be made and kept by small businesses, the number of small businesses affected, the annual frequency that the records need to be made, the amount of time needed for making each record, and the total number of hours for each provision in the first year and then in subsequent years.

TABLE 47.—SMALL BUSINESS RECORDKEEPING REQUIREMENTS

Provision	No. of Small Entities Keeping Records	Annual Frequency	Hours per Record Small Entity	Total Hours, First Year	Total Hours, Subsequent Years
120.6 Monitoring and recordkeeping of SOP's	670	16	.5	5,400	5,400
	225	52		5,900	5,900
120.7 and 8 Hazard analysis and HACCP plan	895	1	80	71,600	0
120.8 Pesticide controls by supplier certificate	676	227	.02	3,100	3,100
120.11 Verification	670	16	2	21,400	21,400
	250	52		26,000	26,000
120.11 Validation	670	1	8 (first yr)	5,400	2,700
	250	2	4 (subsequent yr)	4,000	2,000
120.12 HACCP records	670	1,440	.05	48,200	48,200
	250	8,640		108,000	108,000
120.12 Record maintenance	670	16	1	10,700	10,700
	250	52		13,000	13,000
Totals				323,000	246,000

D. Minimizing the Burden on Small Entities

The RFA requires an evaluation of any regulatory overlaps and regulatory alternatives that would minimize the costs to small entities.

There are two alternatives that the agency has considered to provide regulatory relief for small entities. First, FDA considered and is proposing the option of exempting some small entities from the requirements of these rules. Second, FDA considered and is proposing the option of lengthening the compliance period for small entities.

1. Exempt Small Entities

One alternative for alleviating the burden for small entities would be to exempt them from the provisions of these rules. FDA is proposing to exempt retailers who, for the purposes of this rule, the agency has tentatively decided will include very small businesses that make juice on their premises and whose total sales of juice and juice products do not exceed 40,000 gallons per year and who sell directly to consumers or directly to consumers and other retailers.

Revenue from sales of 40,000 gallons of nonheat treated juice may be approximately $160,000 with annual profits ranging from $1,600 to $16,000 per year (1 percent to 10 percent). This exemption covers most of the very small businesses, although less than 15 percent of the volume of unpasteurized juice. However, packaged products sold by these types of retailers are covered under the labeling rule. FDA requests comments on this exemption.

2. Extend Compliance Period

FDA has also proposed a tiered, extended compliance period giving the smallest firms the most time to comply with the HACCP rule, if such rule is adopted. The proposed labeling rule, however, requires either label changes on the product or labeling 60 days after publication of the final rule. It is proposed that small businesses be allowed to use signs and placards for an extended period before changing the labels on their products. Small and very small firms that produce packaged juices may continue to use signs and placards to display the warning instead of placing the warning on the label of the product until January 1, 2001. On that date all firms producing packaged juice that is not processed with a 5-log reduction must display the warning on the product label. A longer compliance period allows firms to finance large fixed costs out of retained earnings. For a regulation of general applicability across a sector of the economy, it is difficult for firms obtain loans to finance regulatory costs, partially because no increases in profits are expected that could be used to repay the loan. This may be particularly troublesome for small firms that must finance the costs of HACCP controls. FDA is unable to quantify the cost savings of the extended compliance period although one effect of the cost savings will be to reduce small firm failure.

E. Summary

FDA has examined the impact of these proposed rules on small businesses in accordance with the RFA. This analysis, together with the rest of the preamble and the Preliminary Regulatory Impact Analysis, constitutes the preliminary RFA. FDA has determined that these rules are likely to have a significant impact on a substantial number of small entities.

IX. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Bean, Nancy H., and Patricia M. Griffin, ''Foodborne Disease Outbreaks in the United States, 1973–1987: Pathogens, Vehicles, and Trends,'' *Journal of Food Protection*, vol. 53 (September), p. 805.

2-3. Buzby, J., et al., *Bacterial Foodborne Disease: Medical Costs and Productivity Losses* (AER–741), U.S. Department of Agriculture, 1996, p. 42.

4. *Estimating the Value of Consumers' Loss from Foods Violating the FD&C Act*, vol. II, Final Report, September 1988, FDA Contract No. 233–86–2097, p. D–12–13.

5. Cohen, M. L., R. E. Fountaine, R. A. Pollard, S. D. Von Allmen, T. M. Vernon, and E. J. Gangarosa, ''An Assessment of Patient-Related Economic Costs in an Outbreak of Salmonellosis,'' *New England Journal of Medicine*, vol. 299, no. 9, 1978, pp. 459–460.

6. Council for Agricultural Science and Technology, *Foodborne Pathogens: Risks and Consequences*, Task Force Report No. 122, September 1994, p. 51.

7. Personal communication of Gibbs, R., ERS/USDA to David Zorn, Rural Wage for '96, April 22, 1997.

8. Bureau of Labor Statistics, U.S. Department of Labor, ''Employer Costs for Employee Compensation—March 1996,'' U.S. Department of Labor: 96–424, p. 1.

9. Food and Drug Administration, Williams, R., et al., ''Appendix: Preliminary Investigation into the Morbidity and Mortality Associated with the Consumption of Fruit and Vegetable Juices,'' October, 31, 1997.

10. Food and Drug Administration, Zorn, D., and K. Klontz, ''Appendix: The Value of Consumer Loss Relating to Foodborne Reactive Arthritis,'' February 2, 1998.

11. Food Marketing Institute, *Trends in the United States: Consumer Attitudes & the Supermarket, 1996*. Washington, DC: Food Marketing Institute.

12. U.S. Department of Agriculture, *Food and Nutrition Intakes by Individuals in the United States, 3 Days, Continuing Survey of Food Intakes by Individuals, 1989–1991*).

13. Letter from Julia Stewart Daly, U.S. Apple Association to Dr. John E. Kvenberg, FDA, August 14, 1997.

X. Requests for Comments

Interested persons may, on or before May 26, 1998, submit to the Dockets Management Branch (address above) written comments regarding this preliminary regulatory impact analysis on aspects related to labeling for juice and juice products and by July 8, 1998, on aspects of this analysis related to HACCP for juice and juice products. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket numbers found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 24, 1998.

Michael A. Friedman,

Lead Deputy Commissioner for the Food and Drug Administration.

Donna E. Shalala,

Secretary of Health and Human Services.

The following are the appendices to the Preliminary Regulatory Impact Analysis and Initial Regulatory Flexibility Analysis of the Proposed Rules to Ensure the Safety of Juice and Juice Products.

BILLING CODE 4160–01–F

Appendix:

The Value of Consumer Loss Relating to Foodborne Reactive Arthritis

Prepared by David J. Zorn. Karl Klontz supplied key data.

February 2, 1998

Introduction

This appendix details the calculation of economic losses to consumers from developing reactive arthritis (ReA) as a result of a foodborne *Salmonella* infection. The agency requests comments on all aspects of this appendix, especially the link between ReA and *Salmonella* infections and any variation in that link with the different *Salmonella* species.

This study has relied primarily on the work of Thomson, et al. to describe ReA in terms of attack rate, severity and duration. This study was chosen because it represents the most recent primary research into this issue. The study is of post-*Salmonella*-infection ReA in a point source cohort concurrently exposed to the same microorganism. Because the study is specific to a *Salmonella* outbreak, any variation related to ReA resulting from infections of other pathogens is eliminated. Because the study is based on epidemiological follow-up of an outbreak of foodborne illness rather than reviews of clinical reports and medical records, its results are well suited to applying to epidemiological data on cases of *Salmonella* related to juice consumption.

I. Description of Foodborne Relationship

Reactive arthritis commonly occurs in young men and women (and sometimes children). ReA refers to pain, stiffness, redness or swelling in a joint resulting from a previous infection, usually involving the digestive or genito-urinary systems such as *Salmonella*, *Yersinia*, *Shigella* and *chlamydia* infections. (Ref. http://text.arthritis.ca/types/reactive.html)

II. Description of ReA

Stiffness and pain are often worse in the morning. Arthritis most often occurs in the joints of the lower limbs (knees, ankles, toes), but the upper limbs can also be involved. Problems may be in the joints only or involve other body systems such as the eyes, skin, or tendons. Occasionally there is heel pain where the Achilles tendon attaches to the bone, or underneath the foot where the tendons supporting the arch of the foot attach to the heel. Sometimes there is back pain resulting from involvement of the sacroiliac joints.

Women may develop cervicitis (irritation of the cervix) but there may be no symptoms. In men urethritis (discharge from the urethra, difficult or painful urination) may develop. Painful or painless skin ulcers may appear in the mouth, or on the penis, or vagina. These features are similar to those in Reiter's syndrome. Problems with the eyes may result in mild or severe symptoms including pain or sensitivity to sunlight. Sometimes these problems occur many months prior to the onset of joint problems.

Sometimes the disease is self-limiting, meaning it goes away with no remaining problems. Other people have recurrent attacks. Most people manage well with treatment. Ongoing joint problems may result in stiff joints and weak muscles and it often becomes difficult to fully straighten the joints.

Treatments

1. Medication
Short-term antibiotics (usually tetracycline) are sometimes used to treat the initial infection. Non-steroidal anti-inflammatory drugs (NSAIDs), most commonly Voltaren¨ (diclofenac) or Indocid¨ (indomethacin), are used to treat joint problems. Intra-articular steroid injections can help the pain and swelling in single joints. Occasionally, stronger medications such as RheumatrexTM (methotrexate) are used.

Eye problems should be managed jointly by a rheumatologist and an ophthalmologist (eye specialist). Treatment for eye problems is usually steroid drops but oral corticosteroids are sometimes needed in more severe cases.

2. Heat/cold

3. Exercise

4. Protecting Joints
Protecting joints means using joints in ways that avoid excess mechanical stress from daily tasks. There are three main techniques for protecting joints:

Pacing: alternating heavy or repeated tasks with easy tasks or breaks.

Joint Position: using joints in the best way to avoid extra stress. For example, using larger, stronger joints to carry loads, such as a shoulder bag instead of a hand-held purse, and avoiding keeping the same position for a long time.

Helpful Devices: such as canes, luggage carts, grocery carts, special chairs, etc., can help perform daily tasks. Small appliances such as microwaves, food processors and bread makers can be useful in the kitchen. Grab bars and shower seats are important protection against falls.

5. Weight Control

Lifestyle
Along with the physical symptoms of RA, many people experience feelings of helplessness and depression. (Ref. http://text.arthritis.ca/types/reactive.html)

III. Percent of Cases

The incidence of ReA following *Salmonella* infection is often reported to be about 1-2%. Thomson et al. found an incidence of 6.6% (27/411).[1] This is consistent with studies of other epidemics where a dysenteric population forms the inception cohort. The greater incidence reflects the methodology of surveying an entire dysenteric population.

Of those persons with *Salmonella* infections 2.2% (33% of the total that developed ReA) experienced pain that resolved completely within 4 months. Another 2.4% (37% of the total that developed ReA) experienced flares and remissions of pain with periods of wellness in between. Another 1% (15% of the total that developed ReA) experienced waxing and waning of symptoms

[1] Percentages have been recalculated based on the actual number of persons contacted in the 5 year follow-up survey (411) instead of the number of persons which originally experienced acute gastroenteritis (423).

with no periods of wellness. Finally, 1% (15% of the total that developed ReA) experienced chronic unremitting pain.

IV. Duration

Of those persons who experienced pain that resolved completely within 4 months, 22% (2/9) were asymptomatic within 7 days, 67% (6/9) were asymptomatic within 28 days, 11% (1/9) were asymptomatic within 120 days. If symptoms resolved three quarters of the way through each of these periods (i.e., 5 days, 20 days, and 80 days respectively), then the weighted average duration for this group is about 25 days.

Persons in the other categories were still experiencing symptoms 5 years after the onset of the gastrointestinal illness. The duration of ReA in such patients is taken to be for the rest of their lives. Thomson et al. found that the mean age of onset of ReA was not statistically different from the mean age of the infected population. Information from CDC indicates that in 1996 the average age of persons contracting salmonellosis is 27. Using an average life span of 77 years, the average person developing long term ReA following a *Salmonella* infection will experience symptoms for 50 years (18,250 days).

V. Functional Status Codes and Disutility

In order to quantify the disutility that individuals experience from developing ReA, the reduction in mobility and physical and social activity must be scaled. This study uses one type of scaling of these effects following the work of Bush et al. Individuals who become ill experience different levels of functional status in terms of mobility, ability to do other physical activity, and ability to engage in social activities. Functional status disutility represents a degree of departure from perfect functionality.

According to Thomson et al. "Two thirds [18 out of the 27 that developed ReA] continued to have subjective complaints, mostly of minor significance. However, symptoms were severe enough to force a change in work for 4 patients [15%]." The other third showed signs and symptoms of active inflamation that resolved within a 4 month period with no late exacerbations.

Course of Disease	Percent of Total ReA Patients
Resolved Pain within 4 Months	33%
Flares and Remissions with Periods of Wellness	37%
Waxing and Waning with No Periods of Wellness	15%
Chronic Unremitting Pain	15%

For the two categories of patients where there is no indication of change in the course of the illness during its duration (regardless whether the duration is 1 month or 50 years) the functional status code of L35 is assigned. These patients experience no change in mobility but suffer a reduction in physical and social activity.

For the two remaining categories of patients where there is an indication of change in the course of the illness a combination of the functional status codes L41, L42 and L43 is assigned. For the 15% of ReA patients which never experience periods of wellness, codes L41 and L42 were assigned in equal portions ((L41 x .5) + (L42 X .5)). For the 37% of ReA patients which do experience periods of wellness, codes L41, L42 and L43 were assigned in equal portions ((L41 x .33) + (L42 X .33) + (L43 X .34)).

Function Status Level	Mobility	Physical Activity	Social Activity	Level of Disutility
L35	Drove car & used transportation without help	Walked with physical limitations	Limited in work, school, or housework	.3980
L41	Drove car & used transportation without help	Walked without physical limitations	Did work, school, or housework, but other activities limited	.3145
L42*	Drove car & used transportation without help	Walked without physical limitations	Did work, school, or housework, and other activities	.2567
L43*	Drove car & used transportation without help	Walked without physical limitations	Did work, school, or housework, and other activities	.0000

* Code 42 is used whenever the mobility, physical activity and social activity conditions apply and a person is experiencing a symptom. Code L43 is used whenever the mobility, physical activity and social activity conditions apply and a person is experiencing no symptoms.

Course of Disease	Percent of Total ReA Patients	Functional Status Disutility
Resolved Pain within 4 Months	33%	.3980
Flares and Remissions with Periods of Wellness	37%	.1885
Waxing and Waning with No Periods of Wellness	15%	.2856
Chronic Unremitting Pain	15%	.3980

VI. Symptom/Problem Code and Disutility

Additionally, in order to quantify the disutility that individuals experience from developing ReA, the pain and suffering must be scaled. Again, this study uses the scaling of these effects by Bush et

al. Individuals who become ill experience disutility due to the symptoms of illness.

The characteristic pain symptoms of arthritis can be described as pain, stiffness, numbness, or discomfort of neck, hands, feet, arms, legs, ankles, or several joints together. This description corresponds to the Bush et al. Symptom/Problem Complex code of 19. Therefore, the level of symptom-related disutility assigned to each category of patients for each day they experience symptoms is .0344. For the 37% of ReA patients which do experience periods of wellness, this level of disutility is assigned for only two thirds of the time for an average daily disutility of .0227.

VII. Total Disutility per Day per Case

Course of Disease	Percent of Total ReA Patients	Functional Status Disutility per Day	Symptom/ Problem Complex Disutility per Day	Total Daily Disutility	Duration in Days	Total Disutility per Case (in Quality Adjusted Life Days Lost)
Resolved Pain within 4 Months	33%	.3980	.0344	.4324	25	11
Flares and Remissions with Periods of Wellness	37%	.1885	.0227	.2112	18,250	3,854
Waxing and Waning with No Periods of Wellness	15%	.2856	.0344	.3200	18,250	5,840
Chronic Unremitting Pain	15%	.3980	.0344	.4324	18,250	7,891
Weighted Average of Long-Term Cases		.2582	.0280	.2862		5,223

VIII. Medical Cost Estimate

Direct information on the direct medical cost (cost of medical treatment and patient care) per case of ReA is not available. Medical costs for ReA are calculated based on the assumption that medical costs per case of ReA are equivalent to the medical costs per case of the average case of all types of arthritis. Information indicates that in 1992 the total cost in terms of direct medical costs and lost wages of all types of arthritis was about $65 billion dollars. Of this total 24% was

due to direct medical costs and 76% was due to lost wages. (Ref. www.nih.gov/niams/news/lappin.htm National Institute of Arthritis and Musculoskeletal and Skin Diseases "Arthritis: What We Know Today," Debra R. Lappin, Esq., May 30, 1997) According to the National Health Interview Survey, an estimated 40 million Americans have arthritis. Approximately 6 million people are self-diagnosed (that is, they believe that they have arthritis, but have not sought medical attention for it.)
(Ref. http://www.arthritis.org/offices/al/about/demecoinfo.shtml)

Based on this information, the total direct medical cost for all types of arthritis is approximately $16 billion per year ($64.8 billion x 24%). Therefore the average direct medical cost per arthritis sufferer is approximately $400 per year ($16 billion ÷ 40 million). This medical cost estimate is used for long term ReA cases. Discounted at 7% annually the total medical cost for an average case of ReA lasting 50 years is estimated to be $5,860. The medical cost for a short term case of ReA lasting 25 days on average is estimated at $100.

IX. Total Value of Losses per Case

To determine the total value of losses per case associated with ReA it is necessary to add the utility losses per case to the medical costs per case. To do this it is necessary to monetize the value of the utility losses. FDA values a Quality Adjusted Life Day at $630.

Course of Disease	Percent of Total ReA Patients	Total Disutility per Case (in Quality Adjusted Life Days Lost)	Value of Utility Losses per Case (Discounted at 7%) (QALD = $630)	Medical Costs per Case (Discounted at 7%)	Total Value of Losses per Case
Resolved Pain within 4 Months	33%	10.8	$6,800	$100	$6,900
Flares and Remissions with Periods of Wellness	37%	3,854.4	$711,500	$5,900	$717,400
Waxing and Waning with No Periods of Wellness	15%	5,840.0	$1,078,000	$5,900	$1,083,900
Chronic Unremitting Pain	15%	7,891.3	$1,456,700	$5,900	$1,462,500
Weighted Average of Long-Term Cases		5,223.2	$962,000	$5,900	$967,900

Printed Reference

Thomson, Glen T. D., Debra A. DeRubeis, Matthew A. Hodge, Cecilia Rajanayagam, Robert D. Inman. 1995. "Post-*Salmonella* Reactive Arthritis: Late Clinical Sequelae in a Point Source Cohort." *American Journal of Medicine* 98 (January): 13-21.

Appendix:

Preliminary Investigation into the Morbidity and Mortality Associated with the Consumption of Fruit and Vegetable Juices

Prepared by Richard Williams, Thomas Wilcox, Babgaleh Timbo, Debra Street, Clark Nardinelli, Patrick McCarthy, George Jackson, Minnis T. Hendricks, and Elisa Elliot.
Cristina Ford McLaughlin, Judy Lee, Eric Hanson, Tom O'Brien, and Mary Bender supplied key data. Wesley Long, Lee Anne Jackson, Ken Falci, and Ron Lorentzen commented on various drafts.

[April 20, 1998. Note. This document was prepared in the Spring and Summer of 1997 in support of the Preliminary Regulatory Impact Analysis and the Initial Regulatory Flexibility Analysis of the Proposed Rules to Ensure the Safety of Juice and Juice Products. Since the completion of the final version of this document, FDA has accumulated more information, refined its assumptions about the relationships between reported and actual numbers of illnesses, and estimated the distribution of illnesses by severity. The new information and methods are used in the regulatory impact analysis, but not in this document, which has not been changed since Fall 1997.]

October 31, 1997

Executive Summary

Recent outbreaks of illnesses associated with juices have demonstrated the potentially serious human health hazards posed by fruit and vegetable juices. As a component of the cost-benefit analysis for both the HACCP and Labeling rules associated with fruit and vegetable juices, the Center for Food Safety and Applied Nutrition's working group was asked to investigate the morbidity and mortality associated with the consumption of juices and juice drinks. The standard procedure for estimating human health benefits is to (1) estimate the baseline numbers of illnesses and death associated with a technology or compound to be controlled, (2) estimate the likely reductions in those illnesses and deaths associated with various proposed control options, and (3) estimate the values associated with the reduced illnesses and deaths. The report estimates the parameters associated with the first step -- the numbers of illnesses and deaths likely to be associated with the consumption of juice products.

This preliminary investigation included a description of juice products, the estimated levels of consumption of juices, a discussion of production methods, an explanation of how hazards may be introduced into the product, a discussion of the evidence on illness from consuming juices, a description of the human health effects caused by selected microbial pathogens, and a discussion of the physical and chemical hazards associated with juices.

Americans consumed approximately 2.3 billion gallons of the major fruit and vegetable juices in 1995, or 37 billion servings. Orange and apple juice accounted for over 80 percent of juice consumption. The consumption of juice drinks amounted to 2 billion gallons, or 32 billion servings. The working group estimated annual consumption of non-heat-treated juice to be 38 million gallons, or 600 million servings.

The working group found that contamination of juice products may occur at any point between the orchard and the table, but most likely occurs during the growing and harvesting of the raw product. The use of dropped fruit, the proximity of livestock or

wild animals, contaminated ground water, and contaminated humans are possible causes of contaminated fruit.

From 1993 through 1996, the Centers for Disease Control and Prevention outbreak data and U. S. Food and Drug Administration recall data show that juices accounted for 447 laboratory-confirmed cases of illness associated with microbial pathogens. The cases by pathogen included 62 *Salmonella* spp., 86 *E. coli* O157: H7, 85 *B. cereus*, 191 *C. parvum*, and 23 illnesses caused by an unknown pathogen. The associated juice products were apple juice or cider (277 cases) and orange juice (170 cases). The annual average of 112 cases included annual averages of 16 *Salmonella*, 22 *E. coli* O157: H7, 48 *C. parvum*, 21 *B. cereus*, and 6 cases with unknown pathogens.

There is wide agreement that the laboratory-confirmed cases from outbreaks and recalls understate the actual number of juice-related cases, but no consensus exists on the size of the understatement. We estimated the total number of juice-related illnesses by multiplying the average number of laboratory-confirmed cases by factors that account for under-reporting. We based the multipliers on the relationships between annual outbreak cases in 1983-1987 and two widely cited estimates of the number of foodborne illnesses (Bennett et al. 1987; Todd 1989). However, these estimates contain considerable uncertainty.

For *Salmonella*, the two multipliers were 307 and 474, which implied that the 16 annual laboratory-confirmed cases might have been accompanying by an estimated 4,900 or 7,600 total juice-related cases. For E. *coli* O157: H7, the two multipliers were 100 (the default multiplier) and 195, which implied that the 22 annual laboratory-confirmed cases may have been accompanied by 2,200 or 4,300 total juice-related cases. For *C. parvum*, we multiplied 48 annual laboratory-confirmed cases by100 (the default) to get an estimated 4,800 total juice-related cases. For B. *cereus* the two multipliers were 96 and 1,615, so that 21 annual laboratory-confirmed cases implied 2,000 or 33,900 total juice-related